IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION
C.A. NO. 5:96CV91

THE STATE OF TEXAS,
Plaintiff

VS

THE AMERICAN TOBACCO COMPANY, et al.,
Defendant

VIDEOTAPED

ORAL DEPOSITION

OF

ANDREW SIVAK, Ph.D.

August 29, 1997

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ANSWERS AND DEPOSITIONS OF **ANDREW SIVAK, Ph.D.**, produced as a witness at the instance of the Plaintiff, taken in the above-styled and numbered cause on the 29th day of August, 1997 at 9:13 o'clock a.m. before Jamie K. Israelow, a Certified Shorthand Reporter, Registered Professional Reporter and Notary Public in and for the State of Texas, at the offices of Kirkland & Ellis, located at 200 East Randolph Drive, in the City of Chicago, County of Cook, State of Illinois, in accordance with the Federal Rules of Civil Procedure.

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P R O C E E D I N G S

THE VIDEOGRAPHER: We're on the record.

ANDREW SIVAK, Ph.D.,

the witness hereinbefore named, being of lawful age and being first duly cautioned and sworn in the above cause, testified on his oath as follows:

EXAMINATION

BY MR. THOMPSON:

Q. Doctor, could you introduce yourself for the record, please.

A. Yes. My name is Andrew Sivak, S-i-v, as in Victor, a-k.

09:11 Q. I want to make sure I say it right. It's Sivak?

A. Sivak, yes.

Q. Where do you live?

A. In [DELETED]

09:11 Q. You've lived there since 1994?

A. No, I've lived there for just under three years. It will be three years Monday, as a matter of fact.

Q. Okay. And are you currently

09:11 employed?

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A. No. I'm semi-retired and I do independent consulting.

Q. How much of your time do you spend consulting and how much of your time are you retired?

A. Maybe 80 retired, 20 consulting, maybe some months as high as 90/10.

Q. Understood.

A. I -- I am very limited in what I do at the moment.

Q. The client that you are -- have been hired to work in this case for is whom?

A. It's Brown & Williamson Tobacco Corporation.

Q. Okay. And of the consulting that you're doing currently, how much of that is for Brown & Williamson?

A. The only work for Brown & Williamson is the work I'm doing through Kirkland & Ellis.

Q. What other clients are you currently doing consulting work for?

A. I am presently and have for 25 years worked for the National Coffee Association.

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09:12 Q. Okay.

A. As scientific advisor to their scientific advisory committee. I also work for the International Life Sciences Institute
09:13 on their caffeine expert panel. And while it's not active now, I worked for McFall, Sherwood and Shey out of Houston on the Smithson versus Monsanto case, but I haven't done anything on that in, oh, eight, nine
09:13 months. The last thing I heard from Bill, I guess they're still filing motions on that.

Q. Motions may be over in that case. That's on the Brio cases?

A. That's right.

09:13 Q. And that is a community exposure, toxic tort case?

A. That's correct.

MR. McGAAN: Does Brio refer to a place?

09:13 MR. THOMPSON: It is. It's a dump site.

THE WITNESS: That's the dump site that was next to the development that was built.

09:14 Q. (By Mr. Thompson) And you talk

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about Bill Sherwood at McFall?

A. Yeah, right. He -- he was the key contact at -- at McFall, Sherwood & Shey on this case.

09:14 Q. And your client, though, was -- was whom? Do you know?

A. Who was my client? When Monsanto was named -- I think it was the bank that was the lender originally.

09:14 Q. Roosevelt Bank?

A. Yeah. Yeah. That's it. That's it.

Q. Very good. Did your work on the Brio case take you to Texas and to Houston?

09:14 A. Yes.

Q. How often did you go to Texas on the Brio case?

A. Oh, maybe three separate times. I once went down there for a conference, once 09:14 down there for another conference, and then, you know, for a site inspection of the Brio site, and then the third time was for a deposition.

Q. Other than that, have you spent much time in Texas?

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A. No.
Q. You ever been to Texarkana?
A. No. I drove through Texas last summer, but --
Q. That's a long drive?
A. (Witness nods.)
Q. You're a toxicologist; is that correct?
A. That's correct.
Q. What is a toxicologist?
A. Toxicologist is someone who examines exposures to environmental materials -- not necessarily environmental, because they could be drugs or pharmaceuticals, and tries to determine whether there's any effect on humans.
Q. How do you do that?
A. Well, there are a number of steps that one can go through. The first thing one looks at is sort of a physical, chemical step, and it's called structure activity relationships. And there are now some pretty good computer programs, where if you know the chemical structure of the compound that you're working with, you plug into this program and

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it tells you whether it's related to other chemicals that cause effects. So that's usually the first thing you do.

Q. And that allows you, in effect, to group chemicals by families --

A. That's right.

Q. -- based on their ability --

A. You generally put them into three boxes. We're pretty sure that these won't cause because they're pretty far away from the chemical. These are very close and we better look at, and there's always a box in the middle that you don't know what to do with.

Q. Let me --

A. I mean --

MR. McGAAN: Let me just interrupt. I'm sorry. Were you done?

THE WITNESS: No. Yeah.

MR. McGAAN: For the record, let him finish the question.

THE WITNESS: I understand.

MR. McGAAN: It will help the reporter get it too. You guys started to talk over each other.

THE WITNESS: Okay. Sure.

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09:16 Q. (By Mr. Thompson) The purpose of categorizing a particular chemical into one of those three categories is what? Why do you do that?

09:17 A. Well, then you move on to the next step. For -- for a new chemical, like a drug or a pesticide, then you -- it would allow you to establish a testing program because these materials have to be cleared by federal

09:17 agencies, and they require that research be done with respect to the biological effects of these materials.

Q. These would be materials that -- that in the step one, you have determined that

09:17 either they're very close to something that's --

A. Right.

Q. -- questionable?

A. Yeah. They would be either in the

09:17 middle box or the hot box.

Q. Okay. And -- and the goal is to test these materials before you expose a human population to those materials?

A. That's exactly right.

09:17 Q. What types of testing programs?

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A. Well, I think the way things are now set up is the first thing that people do are a set of what are called short-term tests, and those are by and large genetic tests for mutation.

Q. Basically bioassay tests?

A. They're bioassays, exactly right.

Q. And what are the types that are being used today?

A. Well, the battery that's usually used -- the first test that most everyone uses is the Ames assay, which is a bacterial mutation test. Then very often they will do a mutation assay in mammalian cells to get closer to people.

They will often do chromosome damage studies, and there are two kinds. There is -- one is classical chromosome damage, and the other is a method called sister chromatic change.

And finally, they pointed to an in vivo genetic study where they will expose an animal to a chemical, take out its white blood cells and look for chromosome changes in those white blood cells.

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09:19 Q. All of the -- the assays that you described, all four look for changes at the cellular level?

A. Even narrower at the genetic level. It's looking for changes in DNA.

Q. Why do you look for those types of changes as a toxicologist?

A. Two reasons. One, changes in the genetics of a cell can affect future offspring.

Q. Offspring of the cell?

A. Of -- well, if -- if you get the same type of genetic changes in the egg or the sperm of a parent, there could be effects on the offspring.

Q. Birth defects?

A. Birth defects.

Q. Okay.

A. And the second reason is is that there are a lot of carcinogenic materials that are mutagens, so it's -- it's sort of a precancer test, as it were.

Q. And -- and we'll talk about it in more detail, but -- but the process of -- of the development of cancer, if I understand

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correctly, is a multistage process?

A. That's correct, yes.

Q. And -- and the damage at the chromosomal level is one of the -- one of the events that is necessary to those series of steps?

A. It's usually thought that the genetic change is the first defect.

Q. Are the tests that you've described, the three, four tests that you've described, designed to -- to test that first step?

A. Yes.

Q. And so positive results on any of those four tests are -- are an indicator of some activity of the substance at the -- at the genetic level?

A. That's a very good way to say it.

Q. And the point of all that is that in multistage carcinogenesis, that's step one?

A. One.

Q. What other type of short-term tests do you run?

A. Well, after you do the short-term tests, if you're going to do tests to get

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something approved by either FDA or EPA, in other words, if you're going to go down the regulatory route, ultimately, you have to do a chronic long-term animal study, generally in two species, and most often the species that are used are mice and rats.

But before you do that, you do -- have you to set the right dose, so you do a two-week study. You very often will do a three-month study, and that will help you set what the doses should be for the two-year study.

Q. So there's a progression in the chronic studies. You start with a two-week protocol, three-month protocol to set things up?

A. Right.

Q. And then --

A. And then you go for the long one.

Q. Very good. In your answer, you -- you prefaced your description of the chronic studied by saying if you were going to -- seeking to obtain FDA approval, I think there was one other thing that you would do these type of studies?

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09:22

A. Right.

Q. Are there situations where you were not to take the step of doing chronic studies?

09:22 A. I think that would depend on what you saw as a potential exposure of a chemical. You know, if one had really widespread exposure to a material in human population, it would seem that a long-term

09:23 test would be an important thing to do.

Q. Why?

A. If a material were -- had widespread exposure and if it caused cancer in animals, then there's the potential you might

09:23 have a public health problem.

Q. What if you got a substance that has widespread exposure and the evidence suggests that it causes cancer in humans?

A. Repeat.

09:23 Q. If you've got a substance that you know has widespread exposure in human populations and there is epidemiologic data that suggests an association between the exposure and cancer in humans, in your

09:24 opinion, are chronic studies necessary?

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09:24 A. I think that depends on the strength of the epidemiology. If the epidemiology is extremely strong and -- and deep with respect to the number of studies that were done, chronic study would be a waste of time.

Q. And the strength of an epidemiologic study is measured how? And how do you -- as a scientist and a toxicologist, how do you say that this study is a strong study?

A. There are -- I can't remember completely the five things that are used, but there's consistency, coherence, temporal relationship, making sure that the confounders are corrected for. If those are taken care of and an epidemiology study is very strong, contrary to earlier times when a lot of people were not willing to make a causal association based on epidemiology, I think that in the present day that science of epidemiology is strong enough that one can take epidemiology and say, yes, I can determine a cause from this.

Q. Right. And -- and just so we're

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clear. You're not an epidemiologist?

A. I am not a practicing epidemiologist, but over the years, in risk assessment and in my work at the Health Effects Institute and in the Coffee Association, I've had a lot of contact with epidemiologists.

As a matter of fact, I -- I once wrote a short review on the epidemiology of cancer studies related to coffee and published it. I mean, it got published. I'm not practicing, but I'm fairly conversant with the field.

Q. And it's because, if I understand your answer correctly, epidemiology or epidemiologic data is something that you use and rely upon in your work as a toxicologist?

A. Absolutely. Not necessarily as a toxicologist, but as in my broader role as someone doing risk assessments and health assessments.

Q. And epidemiologic data is the type of data that people performing those types of analyses, risk assessments, policy decisions --

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09:26 A. Right.
Q. -- rely upon regularly?
A. Along with the animal studies.
Q. Correct. In your opinion, are positive results on the short-term tests that you've described sufficient for you to draw a conclusion about whether a particular substance is a carcinogen?
A. No.
09:26 Q. What other information do you need besides the short-term?
A. At a minimum, you need a chronic animal study. You need to demonstrate that this chemical will produce cancer in some
09:27 animal test system.
Q. And explain for me why that is the case.
A. In the absence of that, you don't have any confirmation that a chemical will
09:27 produce a cancer. And now that we've got a large body of information, it turns out that among the short-term tests, not all of the things that test positive have been shown to be carcinogenic.
09:27 And by the same token, there are

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09:27 things that have tested negative in the short-term test that when they have given in animals have turned up as carcinogens.

Q. And so that you and I -- when you're using the word "carcinogen" or "carcinogenic," are you talking about something that is a complete carcinogenic or something that is a mutagen?

A. When I'm talking about carcinogenic, I'm talking about something that gives rise to cancers or tumors in some biological system.

Q. So that would be -- I guess that's something I would call a complete carcinogen?

A. Yeah.

Q. As opposed to something you and I talked earlier about the short-term tests?

A. Right.

Q. They identify something that can cause step one in the multistage events, correct?

A. That's right.

Q. And so the fact that a particular substance isn't a complete carcinogen doesn't rule out the possibility that it is a cause

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09:28 in -- in the chain of events?

A. That's not true. If, in fact, a material caused the mutation and then you fed it to rats and mice for two years at

09:29 appropriate doses and got no tumors in the animals at the end, you would say, Yes, it may have caused the mutation, but it's not a carcinogen.

Q. Not a complete carcinogen?

09:29 A. (No response.)

Q. Yes?

A. No. It's not a carcinogen. Again, you're using nomenclature that relates to an area that I was in for a long time.

09:29 It's the area of tumor promotion of initiator, promoter, complete carcinogen. I think that I would prefer to say that if something is a mutagen, but doesn't give cancer when you feed it for two years, it's not a carcinogen.

09:29 Q. All right. If it is a mutagen, does it speak to the potential of carcinogenicy -- genicity? Can I say that?

A. Carcinogenicity.

Q. Thank you.

09:30 A. That's exactly why you do it.

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09:30 It's for the potential. In other words, if you do get a mutagen, then you go on and you test it further to see if you can get a cancer. But it turns out for reasons that we don't understand that not all mutagens give rise to tumors when they've been given in long-term tests.

Q. But if a particular substance is a mutagen, and, therefore, an initiator --

09:30 A. No, you can't make that.

Q. Okay. Go ahead.

A. All mutagens may not be initiators. You don't know that.

Q. What's the distinction?

09:30 A. We have no way to determine that. We don't have the tools that are fine enough at the genetic level to go into DNA and say, This is what initiated DNA looks like. We may when the scientists do their probes better, 09:30 but we don't have that information available to us.

Q. Then -- and I'm still searching for common ground on terminology. If you -- if a test determines that something is an 09:31 initiator, if the conclusion is drawn that it

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is an initiator, then does that qualify as a carcinogen in your glossary of terms?

A. I don't know of any initiators when given in a long-term test, they're not carcinogens. All the ones I'm familiar from in my experience, if it's an initiator, if you give it once and then do a promotional study and get tumors, if you give that initiator repeatedly over two years, you will also get tumors. So I know of no initiators that are not carcinogens.

Q. What about something that is not an initiator, but is a promoter only?

A. What about it? What do you want to know about it?

Q. Well, in your opinion, as something that's just as a promoter, is it a carcinogen?

A. That's an interesting question. The regulators have said no, but you can make an assumption that because of the way our cells divide, and we make spontaneous mistakes about one in a million --

Q. Uh-huh.

A. -- that you could have a promoter

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09:32 modify a spontaneous mistake. It may not have been initiated by anything on the outside, and you can get a tumor. And that definition of promoter could be argued to be a carcinogenic material.

Q. Because without any other external --

A. Yeah.

Q. -- lesion, a -- it could give rise to cancer?

A. It's an internal lesion. I mean, you sort of made it yourself.

Q. Right. Exactly.

A. You didn't apply anything from the outside.

Q. So you get a spontaneous mutation or some flaw in the genetic material, and if there is a promoter present in it, you could lead --

A. Could you lead to a tumor, yes.

Q. What I'm confused about, then, is why -- why is a substance that is an initiator alone -- and let's talk purely theoretical since you said they all kind of fall in the same basket anyway -- why is it not true that

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09:33 something that is an initiator, that causes the initial mutation, in your opinion, why is that not a carcinogen?

And let me give you a

09:34 hypothetical. We've got Substance X that is -- on a bioassay shows to be a mutagen. We can document that it causes change in the genetic material. And if that were all that was occurring in an organism, obviously we

09:34 don't have cancer, we just have damaged DNA, but it is also in the presence of a second chemical or a second substance, which is a promoter. So we've got not the internal initiation, but we've got initiator in the

09:34 presence of a promoter, and it starts the chain of events that leads to cancer.

Is that not a carcinogen?

A. Yes. Yeah. Initiators are -- are defined as thing that begin the carcinogenic

09:34 process, so that if you go with your scenario, and I'm very familiar with that, having spent a lot of years in that research, yeah, it's a carcinogenic material, because without it, you would not have gotten tumors.

09:35 Q. And so when we have a -- we have a

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complex system where we've got a number of insults, all of which may be necessary to lead to the end point, cancer --

A. That's correct.

09:35 Q. -- is that correct?

A. Yeah.

Q. And any -- any insult, any chemical which -- which is a cause of one of those steps that are necessary is a cause of 09:35 the end point?

A. It leads to the end point, yeah. It leads to the end point.

Q. It's not the cause, but it is a cause?

09:35 A. But it's a contributing cause.

Q. Very good. When we started talking about toxicology and drugs and pharmaceuticals, I thought you said there were three things. One was the structure activity 09:36 analysis?

A. Right.

Q. The second was testing programs. What is the third?

A. The second was the short-term 09:36 tests.

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09:36 Q. Right.

A. And the third piece was the animal, long-term animal bioassay.

Q. Okay. Anything else in the kind of general step-by-step analysis?

09:36 A. Well, you know, with respect to pharmaceuticals, they do do short-term human tests before drugs are approved. There's a special form that you fill out for FDA, and they allow -- you know, that's how medical students often make their money in medical school, by being shot up with --

Q. Are there special considerations that -- that you and others in the scientific community take into account before making a decision to do human testing?

A. Again, the only place where human testing is authorized and justified, and that's the pharmaceutical agents.

09:37 Q. And why is it -- why is it justified, in your opinion, in that narrow category?

A. Yeah, I -- you know, very clearly, in a pharmaceutical agent, the final intent is to give this thing at a dose that's going to

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cause a biological effect in a human, to cure a disease or relieve some pain or some sort of an effect. And the FDA has determined that it's appropriate to do some short-term tests in humans to determine in a small group of humans at a low dose whether you're going to get into trouble.

And they also do some pharmacology in humans too to determine what the fate and distribution of these materials are before they give final approval.

Q. And I guess the point of that is that before you expose the population at large to something, you want to understand the possible harmful effects?

A. Yeah.

Q. And at what dose harmful effects might occur?

A. That's right. As a matter of fact, before, you know, anything is approved, clinical trials are held. I mean, they actually go into hospitals and they treat people before FDA -- and that's why approvals take six, seven, eight years for drugs.

Q. In -- in the process that you're

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09:38 describing, it sounds like it is a significant issue if something is a drug or considered a drug, then it invokes additional requirements in terms of the analysis that a toxicologist might go through?

A. Exactly right. For example, if you compare the way EPA asks you to formulate tests for pesticides, you go through the short -- the short activity, short-term, two-year study. That's the end of it.

Q. Uh-huh.

A. Whereas, that's only really the beginning of it if you're going to do a pharmaceutical, because you've got to go through the entire human and clinical trials before you can even submit your application to be approved.

Q. That's much more onerous than -- than the -- I guess, when you use the example pesticides, that's just what, what category --

A. That's an enviro -- potential environment exposure. That's why EPA does it, that, you know, there are pesticide residues on foods. And there have been some, you know, famous or infamous issues, the Alar thing out

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09:39 in the state of Washington which raised cain with the apple growers, those kinds of issues.

Q. So at that level, the concern is if you are going to put a product or put a chemical, I guess, out into the environment at large --

A. Right.

Q. -- you want to do an analysis?

A. That's right. To make sure that if people are exposed to it, that they're not going to be harmfully affected.

Q. And the pharmaceutical category is different because the inquiry is, I guess, if you are going to intentionally expose human beings to it, that invokes a different level of scrutiny?

A. That's right. And they deal with what they call therapeutic balance, how much toxicity are you going to allow to get the positive effect of the drug.

Q. And it's a --

A. It's balance.

Q. -- a weighing --

A. It's a balance. And for something, you know, things like penicillin,

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except for people who are allergic to it, it's virtually nontoxic. You can take large doses of it. But some of the doses they treat high blood pressure, cardiac drugs, I mean, there's a very high balance of how much people can take and not get sick from the drug and have their blood pressure go down, and that's -- that's a very delicate balance.

Q. And in the example of penicillin, then, that would be something that the benefits are enormous and the risk is very small?

A. Very small, right.

Q. As in the pharmaceutical sense, if the balance gets close, what is generally the -- which way do we err?

A. You err on -- always on patient safety, always on patient safety. If the balance gets too close, the drug won't be approved by -- by FDA.

The only place where they don't is really in antitumor drugs.

Q. Partly because --

A. You know, for example, if you have Hodgkin's disease and if I can take a material

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09:41 that's going to give me 15 more years of life, I'll take the chance of lymphoma at the end of 15 years rather than die next year.

Q. Sure. And -- but in that case, the -- the risk benefit scales have kind of been tipped?

A. Yeah. It's a different -- a different equation.

Q. Based on what we've just talked about, I would assume it would be accurate to say there are substances that would be approved and legal to use as a -- you know, as a chemical, as a pesticide, as something in the environment at large that would never be approved for use, direct and intended use in the human population?

A. Pesticides especially. Pesticides are poisons. I mean, they're meant to kill insects. They're meant to kill other plants. I'm not so worried about the antiplant things, but the antiinsect drugs are extremely potent agents.

Matter of fact, a lot of them act like nerve gas. I mean, what they do is they kill the nervous system of the insect.

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Q. Uh-huh.

A. And that's why whenever you buy a bottle of pesticides, there's an enormous warning label on it, wash your hands, don't expose yourself to it.

09:42

Q. What kinds of things that -- if we've got a potent pesticide that stuns a roach into submission, what does it do to a human being?

09:43

A. Well, you can have serious neuromuscular problems from them. Most of these are -- are nerve poisons, and that's how they kill the insects, and the chemical doesn't know when it sees a nerve whether it's a human nerve or an insect nerve. If it's a human nerve, you're likely to end up with some severe problems.

09:43

Q. And let's stay with that example for a second. As a toxicologist, where do you go to find out -- if you've got a chemical that's being touted as a pesticide, where do you go to look for whether it's going to have an unintended effect on human beings?

09:43

A. All of the approved pesticides, the entire database is filed with EPA, and you

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could either write -- I think that may be available even on the Net now, that you could go into the EPA pesticide files and say, Tell me everything I need to know about 24-dimethyl chicken fat, and it would lay out, you know, short-term tests, these were the results; subchronic tests, chronic tests, these were the results.

Q. Uh-huh.

A. And EPA would be the place to go to for pesticide data.

Q. As a toxicologist -- or let me ask it in two phases.

As a toxicologist, do you get involved in the weighing that you just described, the risk benefit analysis?

A. I haven't recently.

Q. Okay.

A. When I was at Arthur D. Little, we would work with companies on -- on making those decisions. We often did tests for them in my laboratory up there, and then we would sit down with our people and sort of look at what the data said and -- and help them to come to some judgments about things.

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09:45 Q. And in -- in the circumstance like that, what you're talking about is a judgment based on the priorities -- well, I guess, the concerns of the -- of the individual or group of individuals making the judgment?

A. Yeah, and sort of -- and which regulatory barn you're in.

Q. Judgments would be different if you're in the pesticide barn than if you're in the pharmaceutical?

A. Than if you're in the pharmaceutical barn. You're exactly right, exactly right.

Q. And that kind of leads me into a question I wanted to ask, which is: Who -- who are the types -- who relies upon the work that you do as a toxicologist? Who makes decisions based on that work?

A. When I worked at Arthur D. Little, the various corporate people that we worked for would make decisions based on that data.

When I was at the Health Effects Institute, the automobile companies would look at what we did and -- and make decisions based on -- on -- on what we found.

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09:46 And I guess the coffee situation is different because caffeine in coffee is not regulated because it's a natural material, so we do the research because caffeine ends up being something that people blame for everything --

Q. Uh-huh.

A. -- with no real support, but they do anyway. But, you know, everything that -- 09:47 that the scientific advisory group does for the National Coffee Association goes back to Procter & Gamble for Folgers and Nestle, and the people who support it.

Q. And with respect to caffeine, if I 09:47 took caffeine out of coffee and, you know, a had a, you know, glass of caffeine, Coke --

A. It says so right here.

Q. Uh-huh. At what point does caffeine?

09:47 A. That's -- that's regulated.

MR. McGAAN: Let's go back to the question and answer. You guys are talking. --

A. I'm sorry. It's not a drug. It's 09:47 food additive.

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09:47 Q. (By Mr. Thompson) Okay.

A. And caffeine in coffee is not regulated because it's a natural material. Anytime you add caffeine to ice cream, cake,
09:48 Coca-Cola, it becomes regulated, and it is regulated by the Food and Drug Administration as a food additive.

Q. And so we have, really, more than one level. We have something like caffeine.
09:48 And would you agree with me that caffeine has pharmacological effects on the human body?

A. It sure does.

Q. I hope so because without it, I would be in deep trouble.

09:48 In coffee, because it is considered a natural occurring substance in coffee, it is not regulated at all?

A. That's right.

Q. In the example you gave me of
09:48 Coca-Cola, because it is a product that is manufactured, and the caffeine is an additive --

A. That's right.

Q. -- it is regulated by the FDA?

09:49 A. As a food additive, that's

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correct.

Q. And in that category, in the category of being an additive that is regulated by the FDA, what -- what types of criteria does a substance have to satisfy?

A. The criteria that we listed before. It's got to go through the entire testing scheme, which caffeine had a long time ago. And caffeine may be one of the most tested substances out there because every time there was a new scare, as it were, a whole new set of tests were done. So there's an enormous database on caffeine, in experimental work. And there's an enormous human database on caffeine related to almost every disease related to mankind.

Q. And -- and with regard to the scares related to caffeine, how has the scientific evidence played out over time?

A. Well, what's happened is that, for example, I told you I -- I did this review of all of the studies that looked at caffeine and coffee consumption related to cancer. When you go back and look at that data, there are a few that have relative risks of 1.2, 1.4, but

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there is no credible evidence in all of that data -- and there's something like 65 or 70 studies -- that coffee or caffeine consumption plays in role in exacerbating cancer.

Q. Because of the lack of consistency from study to study?

A. Well, no. It's just that the regulative risks are all at 1 or 1.1. It's -- I mean, it's -- you're not talking about anything that's -- that's epidemiologically significant. And the good news is, of course, for colon cancer, the relative risks are lowered to about .75, so that there is good evidence that if you drink coffee, your risk of colon cancer is decreased.

Q. At what point, in your opinion, in doing this type of evaluation does epidemiologic data become significant? At what relative risk?

A. I'm not an epidemiologist, but my -- in watching them operate, that anything -- anything 2 two, they fight about. You know, if you've got 1.4, 1.5, if a study has been done really immaculately, and all the confounders have been selected for, the

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09:51 statistics have been done, maybe 1.5 means something.

Q. Uh-huh.

A. But, again, in my observation -- and this is just an external observation, I'm not an epidemiologist -- anything below 2, people sort of shrug their shoulders about it.

Q. As that number grows, then, the concerns -- not -- does as the number grows, the confidence becomes greater?

A. Absolutely. Because as the number grows, even if there are competing factors, because most of the confounding issues only change the numbers by a few tenths. Even if they were all there, they would not change the number by a whole integer. So as the number gets larger, then your confidence goes up a whole lot.

Q. And if -- I guess my basic understanding of epidemiology is the point is try to adjust for confounders if you can, but you're not always able to do that?

A. That's true.

Q. But to the extent that the relative risk grows and gets bigger and bigger

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09:52 and bigger, if you've got a very strong number, a very high relative risk, then that is a study that is probably not -- that the association is probably not related to some
09:53 unknown confounder?

A. I think that's correct.

Q. And if you -- if you took that type of finding and found it consistently over time, that would also be an indicator that the
09:53 confounders aren't causing results?

A. That's correct.

Q. In our coffee example, and I try to be -- drink decaf every now and then unless, you know, they take caffeine out of
09:53 it -- they claim they do -- then I often will blame -- you know, half a cup -- cheat and do half a cup of decaf and half a cup of coffee and it's supposed to make -- or half a cup of regular?

09:53 A. Procter & Gamble now sell that.

MR. McGAAN: Only a Plaintiff's lawyer would say decaf is a claim. I believe them.

MR. THOMPSON: I disbelieve
09:53 them.

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09:53 MR. McGAAN: And I don't drink it.

THE WITNESS: The decaf, only about one percent is left.

09:53 MR. THOMPSON: I understand. See. I told you.

MR. McGAAN: That's right.

MR. THOMPSON: It's still there.

09:53 Q. (By Mr. Thompson) If, however, the company takes out most of the caffeine and markets the product called decaf?

A. Right.

Q. If a company added more caffeine

09:54 as an additive in our similar -- similar to our example of Coca-Cola, it would be regulated by the FDA as an additive?

A. If someone added caffeine to coffee?

09:54 Q. Yes.

A. Yeah.

Q. If I wanted supercaf?

A. Anytime you modify a food product by adding something to it, then the FDA steps

09:54 in, because then it becomes a food additive,

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and food additives are under their legal jurisdiction.

Q. Okay. What if I added something -- and you know where I'm going with it. What if I added something to coffee that increased the -- something other than caffeine, but that chemically increased the level of caffeine in the coffee, made it more available?

A. From a physical/chemical point of view, that's not possible.

Q. Okay. So I don't have to worry about that problem?

A. Caffeine is extremely water soluble, and as a matter of fact, caffeine because of its solubility is often used in experimental studies to determine body water because it's completely absorbed immediately, so there's no way you can get more caffeine out of coffee than there --

Q. Than there's already --

A. -- than there is already there. There's no way.

Q. The only way you can do it to get supercaf is to actually add coffee -- add

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caffeine?

A. Yeah. Right.

Q. You told me how long you've been a toxicologist, I'm sure, but I've forgotten. How long have you been in this business?

A. Oh, I guess since I first went to ADL, and that was 1961. Thirty-six years.

Q. You said proudly.

MR. McGAAN: Sheepishly.

Q. (By Mr. Thompson) I have heard or seen, read as toxicology referred to as a science of poisons.

A. Yeah, although -- you know, from the famous quote of a Sixteenth Century Parcellus who said, All things are poisons. It's the dose that matters. That's -- that's Toxicology 101, day one, that's the first thing that's up on the board.

Q. If the dose is the poison something --

A. Well, what he said is that all things are harmful; it's the dose that matters.

Q. And the inquiry and the science of toxicology is to try to determine at what

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level a substance is a poison?

A. That's correct.

Q. You've -- we've talked kind of in generalities about a couple of different things you've worked on, but I want to get a feel. You've talked about coffee?

A. Right.

Q. What other types of substances have you personally been involved in evaluating? And -- and in general --

A. Yeah.

Q. -- because I don't want to talk about specifics.

A. Again, at Arthur D. Little, we were involved a fair amount with the pharmaceutical industry, so we ended up testing a variety of chemical materials over the years. And as the -- as the new biotech stuff came along, we even ended up testing some of the new biologicals, which is a real challenge because that's a whole -- a whole different ballgame.

And then from the chemical point of view, there are sort of two things. One is the actual chemistry in biology where we

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09:58 actually did tests, and then there's a whole section where we studied and wrote reviews. We worked for the Soap & Detergent Association, and over the period of, oh, 15 years, wrote three separate versions of really complete reviews of all the surfactants that are used in detergent products, all the way through from the ecological to the human health things. And those are published. I mean, they're out in the open literature. The last ones were finished just as I was leaving ADL in '88 and '89.

And then there's this big project we did for the Air Force.

Q. And what was that?

A. This was called the Restoration Renewal Project. The Services, of course, not having been under EPA regulation, were atrocious. We used to dump gasoline chemicals in the soil, and most military bases are a nightmare.

The Air Force hired us to prepare for the engineers and toxicologists guide books for the chemicals that concern them. And my recollection, there are about 30 or 40

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09:59 separate chemicals, in addition to stuff like diesel oil, aircraft fuel, which are almost impossible to deal with toxicologically, but we wrote monographs on each of these
09:59 materials. It included the chemistry, the distribution in the soil, the toxicology.

And then our occupational safety and health people came in and wrote safety descriptions so if you're going to go in and
09:59 clean the soil out that has whatever the chemical is, here are the cautions you ought to take. And that -- that was a very big project. That ran -- that ran for five years, and I think we got about 1.3 million to do
10:00 that.

Q. Kind of a massive toxic waste cleanup for the government?

A. That's right. That's exactly what it was.

10:00 Q. And I kind of --

A. We wrote -- my group was responsible for writing the monographs on the -- on the toxicology and human health effects. I was also the project manager.

10:00 Q. In your opinion, was the absence

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of regulation, the fact that the military bases weren't subject for regulation, in part, the cause --

A. Yeah.

Q. -- of this mess?

A. Yeah. They -- they just -- you know, any industry that did that would have found itself in court in a minute, and subject to, you know, hundreds of thousands of dollars worth of fines, but the military was outside the pale.

Q. And in your experience, doing the kind of work that you've done, the presence of some kind of regulatory framework provides at least some kind of checks and balances to that kind of conduct?

A. Oh, yes. I -- now, at ADL, we worked with industry an awful lot. I mean, they used to come to us, because again, unlike some consulting agencies, they told us -- we call it like it is. If you don't want the truth, go somewhere else, and people respected that.

And my experience has been that the large majority of major companies in this

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country were very responsible and -- and were very concerned about the environment and -- and spent enormous amounts of money to do -- to do what was the right thing.

Q. Because they were subject to regulation or just because it was the right thing?

A. No. I think it was corporate responsibility. I think it was internal rather than external.

Q. You also made a comment that -- that the diesel fuel and the -- I think the aircraft fuel was almost an impossible task. Why is that?

A. Well, those are extremely complex mixtures. When they're put into the soil, they're going to change, the soil microorganism is going to change them. You have no idea what the chemistry is that you're looking at unless you get into a really very sophisticated and expensive chemical analysis program. So we did the best we could.

I mean, we -- we -- we -- we made the assumption that things were not changed, that -- that diesel was this collection of

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aromatic hydrocarbon or aliphatic hydrocarbons, and this was the toxic effect of them. But now, they were, Do a risk assessment on crankcase oil. I said, Come on.

Q. What is it?

A. Yeah. Right. We can't do that. So there were -- there were, I think, two or three things where I drew the line. I said, Scientifically, I cannot put my name on a risk assessment for this material because the unknowns are so enormous that I'm not going to sign off on that. And they finally -- they agreed to that.

Q. And because of your uncertainty, you -- your choice or your position was, I'm going to err on the side of being conservative. I'm not going to make a statement about something I don't know enough about?

A. That's right.

Q. And if I understand what you've said that the diesel or jet fuel presented a problem for two reasons. One is, it is a complex mixture. When I say "diesel fuel," there's not a chemical, molecule --

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10:03 A. Diesel fuel is definable. It's a mixture of maybe 12 or 15 different aliphatic hydrocarbons and different mixtures. It's not like some complex mixtures, but it's a 10:03 definable mixture once it comes out. Once it goes into the soil, then, you know, you have no idea what it becomes. And we then agreed with them that in the absence of knowing what happens to it, we will just do our analysis on 10:04 what we think the current material is.

Q. Okay.

A. And that -- you know, that was sort of where we came out on it.

Q. But would you agree with me that 10:04 in any risk assessment, that the -- where you know you've got a complex mixture and where you know there is a mechanism for change, whether it be microbiotic or chemical or, I guess, metabolism of a human, that it is not 10:04 sufficient to just test the beginning constituents and make conclusions about that?

A. That's true.

Q. You need to get an answer about what, in fact, the exposure is that you're 10:04 worried about?

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10:04 A. Yeah. When you do risk assessment, exposure is a driving force. It's not the toxicology, it's the exposure, how much of what are people exposed to.

10:05 Q. Any other kind of general categories of work that you've done? You've talked about coffee. You've talked about the military.

A. We -- we did a big job, and of 10:05 course, now with all the news about -- about the Gulf troops exposed to chemical warfare agents, we did another very big job for the Air Force where we reviewed -- and this is back in the early '80s -- we reviewed their 10:05 medical protocol for treatment and prevention of chemical warfare injuries. I hired the former assistant surgeon general of the Army to work with me on it. And then I hired a local guy who was a former retired medical 10:05 physician from the Army.

Q. Uh-huh.

A. And the three of us, along with our team, reviewed the history of all the chemical warfare agents, how the Air Force was 10:06 now treating them. We then spent a year and a

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half visiting all the NATO countries, getting all the information we could, and prepared a monograph that said, you know, here's what we know. Here's what you're doing. Here's what other people are doing. This is our recommendation for where you guys ought to end up.

And that, of course, was also a very big project, and -- and it turns out that they had not looked at that in 20 years when we picked it up, which was a little scary if you're in the Air Force. But it turns out they ended up -- I don't know whether it was on our account or not, but the troops out there were pretreated with pyridastigmine. When they had a chemical warfare alarm, they took this preventive agent.

Q. We've been going about an hour. Why don't we take a quick break?

A. Sure.

THE VIDEOGRAPHER: We're off the record.

(A recess was taken.)

THE VIDEOGRAPHER: We're on the record.

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Q. (By Mr. Thompson) Doctor, we talked about the work you've done, and one thing we haven't specifically talked about, but the reason we're here, is you have also done some work on cigarette smoke.

A. That's correct.

Q. And just describe for me the kind of work that you have done, in general, that relates to cigarette smoke.

A. Well, there are two venues. One was at NYU.

Q. Okay.

A. I -- when I went there in 1964, I joined a group with Benjamin Van Duuren who was already working on the chemistry of cigarette smoke condensate. Matter of fact, Van Duuren was one of the few people who began to chemically identify the materials in condensate, and I was brought aboard as a biologist. And with Van, we worked on cigarette smoke condensate for a number of years, published a number of papers, which are on my list.

Q. Uh-huh.

A. And then in the meantime, I also

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developed an individual research program using cell culture systems. That was primarily to do mechanistic study, looking at the mechanisms of tumor promotion.

Q. Let's talk about NYU, first.

A. That was NYU, right.

Q. Okay. These were both at NYU?

A. Yeah. Right. I was in the laboratory, and I had two jobs. One as the biologist. And as the biologist, I was responsible for scoring and examining all of the experimental animals on tests, including the ones on cigarette smoke condensate, and I also parallel had my own cigarette project.

Q. Cigarette smoke is similar to our example of diesel fuel or jet fuel in that it is made up of a number of different chemicals or molecules; is that correct?

A. It's far more complex. I mean, diesel fuel and jet fuel have maybe 15 or 20. I don't know if they've ever counted the numbers of things in cigarette condensate. The numbers run up into the thousands of different chemical entities.

Q. And for the reasons that you and I

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discussed earlier, therefore, the evaluation of cigarette smoke from a toxicological perspective is a difficult task?

A. Yes, it is.

Q. You worked on a team that was involved in identifying some of the constituents of cigarette smoke. Is that what you --

A. That's correct. Van Duuren was the chemist, and the basic thrust of the contract we had with the National Cancer Institute was to see whether -- and Wynder had already started with some of this -- was to find out where the active material in -- for mouse skin painting were, which fractions were they in. If you could get the fraction out, could you identify the specific chemicals. And if you could identify the specific chemicals, could you get rid of them?

Q. That was the point, is to try and identify --

A. Right.

Q. They were searching for the specific, you know, agent so that they could try to get rid of it?

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10:28 A. So that we could identify them, and then whoever was responsible would know that, and -- and could try to get rid of them.

Q. What kinds of chemicals are in cigarette smoke?

10:28 A. You name it. There are straight chain aliphatics that come from waxes.

Q. I'm sorry. What -- what's a straight chain aliphatic? To a lay person, what kind of chemical is that?

10:28 A. Things ranging all the way from propane up to octane, all the way up. There are a lot of waxes on -- on tobacco leaf, and the waxes are, in fact, what give rise to a lot of the other materials.

10:28 Q. And we talked about this process before. The waxes go in, and --

A. And the leaf goes in.

Q. And when the cigarette --

10:29 A. When it's burned, it just --

Q. Something else is produced?

A. All sorts of other things are produced, right.

Q. They are the products of

10:29 combustion --

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10:29 A. The combustion.

Q. -- pyrolosis? Is that a term that was used?

A. The pyrolysis product.

10:29 Q. Okay. So the straight chain aliphatics --

A. Aliphatics, aliphatic alcohols, a large population of polycyclic aromatic hydrocarbons, which have entertained a lot

10:29 of -- that's where most of the action has been, a whole bunch of nitrated compounds, a bunch of nicotine and nicotine derivatives, and that's only a small list. I mean, I -- my guess is that there may be compounds of almost

10:29 every chemical entity in that being -- it being so complex as it is. But those are the chemicals that have generated the most interests from a biological activity point of view.

10:30 Q. And -- and when you say almost everything, it's been reported that there -- for example, benzene in cigarette smoke?

A. There's a small amount of benzene, that's true.

10:30 Q. Back up to the PA agents or

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10:30 polycyclic aromatics hydrocarbons. You said most of the action is there. What do you mean?

A. Well, what happened was that in the early days, again, way, way back, even in the -- even in the '30s, it was found that things like benzo(a)pyrene, which was already known as a carcinogen, were present when you burned hydrocarbons. And because a carcinogen was present, people looked for it in cigarette smoke and they found it.

Q. Is that the primary PAH in cigarette smoke?

A. No. I don't know which from a mass point of view is the primary PAH. Of the ones that we know, it's the one with the most activity.

Q. Most biological --

A. Most biological activity, but it's not -- from a mass point of view, it's not -- it's not the heaviest.

Q. And -- and much of the action involved in investigation of the role of the biologic activity of the benzo(a)pyrene?

A. And, again, in our laboratory,

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10:31 because Van Duuren was interested in this class of chemicals, we looked at a whole series of aromatic hydrocarbons, all of which were present in cigarette smoke condensate.

10:31 Q. And in your work, you found or you-all found -- in Texas terms, you-all found, that benzo(a)pyrene was both a promoter -- both an initiator and a promoter?

A. No. We found that benzo(a)pyrene

10:32 was an initiator and a whole carcinogen.

Q. Okay.

A. Along with several other polycyclic aromatics.

Q. And so going back to our

10:32 discussion earlier, it falls into two different slots, as initiator only, correct?

A. It's an initiator.

Q. And it is a complete carcinogen in our terminology. When you say "whole

10:32 carcinogen," that's what you mean?

A. Yes.

Q. Benzo(a)pyrene is a carcinogen?

A. Yes.

Q. And that is something that has

10:32 been known since before you started working

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for --

A. Oh, yeah. It's been known for 50, 60 -- before that it was known in the '30s. English chap, Davies, first isolated it from tar, and they found that it was carcinogenic back in the '30s.

Q. What other substances in smoke are carcinogenic?

A. The other substances that are potentially carcinogenic are nitrosamines, the nitrosamines that are nicotine related.

Q. Tell me what you mean by that.

A. There is a set of, I think, three of them, the most potent of which has the letters NNK, and the people at the American Health Foundation, and the people there, with Ernie Wynder, have done a lot of work on that. And they isolated an NNK from cigarette smoke condensate, and they tested it biologically, and they to found it to be a very potent carcinogen.

Q. So when we see discussions in literature, general discussions in nitrosamines, probably we're talking about NNK as a subset?

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A. Yeah. There are -- and there's -- NNN, NNK, and three of them that I think that -- that Huffman identified that were nicotine related. I just can't bring up which of the -- the specific names of them.

Q. And when you use the term, you describe it as being "nicotine related," how are those nitrosamines -- nitrosamines different from --

A. Well, what happens, the nitroso function is -- is on the nicotine ring, whereas other nitrosamines, the ones that are of concern are aliphatic, diethyl nitrosamine, nitrosamine, which experiments used all the time, they're chemically a different beast.

Q. Because they're not connected to the nicotine?

A. No, not at all.

Q. Because of the relationship between the nicotine and this subset of nitrosamines, are they always present together?

A. I'm not quite sure I understand.

Q. Could a substance that doesn't have nicotine have these nicotine-related

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nitrosamines?

A. It would be highly unlikely.

Q. And similarly, if you reduce the amount of nicotine in a substance, would you agree that it would reduce the amount of nicotine-related nitrosamines?

A. Likely it would.

Q. Do you know whether or not there is a way to, in effect, rid the nicotine of these related nitrosamines, scrub it, clean it, use a solvent to dissolve them off?

A. I'm not enough of a chemist to know the answer to that.

Q. Okay. Do you know whether that's been an inquiry in terms of --

A. I don't even know that.

Q. But at any rate, and, obviously, kind of a just by gut reaction would be that one way to reduce the level of these, in your words, potent carcinogens, would be to reduce the level of nicotine in a substance?

A. If the level of nicotine were lower in a substance, then it's likely that the level of NNK would be reduced.

Q. The -- we've talked about PAHs.

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We've talked about NNK. Are there other known carcinogens in smoke, to your knowledge?

A. Not that I know of. I mean, those -- those are the materials that have been looked at. There may be because when all the calculations are made, for the mass of known carcinogenic hydrocarbons, you come up shy. There's just something that doesn't fit.

Q. The sum is bigger than the --

A. Than what you have.

Q. The whole is greater than the sum of its parts?

A. Of its parts, yeah.

Q. Which is similar to what you described, at least with regard to your concerns for diesel fuel in soil?

A. Yeah. Except there, we don't know what the biological activity of those materials are. They could be inert. I mean, if you oxidize, say, octane into octanol, from a biological point of view, you're not going to cause much problems. You know --

Q. The NNK nitrosamines have been identified as carcinogens for how long?

A. Gee. When did they do that.

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10:38 Q. Huffman and Wynder?

A. It was -- Huffman really who did that early work, and I just don't recall that, you know. It's been at least 15 years. It 10:38 may be even longer. As I get older, it may be 20 years.

Q. We've talked about complex mixtures of substances, and in the example of cigarettes, we've talked about all of the 10:38 constituents of smoke. From a toxicologic standpoint, would it be fair to say that the more you put in to a product, the more different kinds of chemicals and substances you put into a product, the more you create 10:39 the possibility for this vast array of --

A. I'm not --

Q. -- of products?

MR. McGAAN: Wait till he finishes.

10:39 Q. (By Mr. Thompson) Let me finish the question. Sorry. I'm thinking of a good word -- of products of combustion.

A. That depends on the chemistry of the materials.

10:39 Q. Okay.

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10:39

A. I don't -- I don't think one could say, This is a rule.

Q. Uh-huh.

A. It we depend very much upon the chemistry of the material you put in.

Q. So you might be able to add -- you might add something to a blend that would, in fact, simplify the downstream constituent and product combustion?

10:40

A. I'm not sure that you can do that, but I'm not sure -- there are situations I can conceive of where you could add materials that would not add to the numbers of new materials that are --

10:40

Q. You think that's what happens? You think that perhaps adding flavoring and additives, humectants and things like that makes it more complicated?

A. To some degree, but a lot of those come through on changes.

10:40

Q. Just vaporize?

A. Yeah. They become -- that's why they taste them. That's were menthol comes through.

10:40

MR. McGAAN: Did you say

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10:40 menthol?

THE WITNESS: Menthol, m-e-n-t-h-o-l.

Q. (By Mr. Thompson) The work that you-all did at NYU that related to the condensate, then, was -- was mouse painting studies, basically?

A. Yeah. There were some -- a few injection, but most of them were mouse skin painting studies where we looked at whole tar, we looked at fractions of whole tar, and then we looked at individual aromatic hydrocarbons.

Q. Okay.

A. And then in my project, after I had developed an assay, the Department of Agriculture came to me as part of a program they were running and had me do in vitro promotion tests on condensates from different types of tobaccos, high nitrogen, low nitrogen, high nitrate, low nitrate, and they made cigarettes -- this was part of the Gio Gori's safer cigarette program, and I had a small contract to -- to look and compare different condensates from differently cultivated tobaccos using cell culture assay

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systems.

Q. On the step one, the mouse painting, the subcutaneous injection studies that you did, when you say "whole tar," what is your -- what did you use as whole tar? Was it --

A. We -- we got cigarette smoke condensate from -- I guess it was Freddy Bock who made it, who was one of the contractors for the safer cigarette people. And I think Fred made the condensate up in -- up in Buffalo and then shipped it to us, and then we would dilute it and paint it on the backs of mice.

Q. How fresh was the condensate? Do you recall?

A. I forgot what the frequency is that we would get it. I suspect it may have been monthly or every other month we would get a bottle, but don't hold me to that. That's sort of a dim recollection. I mean, that's 30-some years ago.

Q. In your review of the BATCo B & W documents, did you run across some work that they did that fresh condensate had more

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10:42 biologic activity than old or stored concentrate?

A. Right.

MR. McGAAN: Aged.

10:43 MR. THOMPSON: Aged. Thank you. That's a good one.

Q. (By Mr. Thompson) The cell culture system specifically that you're talking about, describe that for me if you 10:43 could.

A. This was something that -- I backed into it, really. I -- I -- I was working with -- as was a lot of Van Duuren's group -- a model tumor promoter. We called it 10:43 PMA. All of people call it TPA. It's a phorbol ester. It's an extractor from the euphorbia plant. And it's an exquisite mouse skin tumor promoter. You can initiate with a small dose of one of the aromatic hydrocarbons 10:43 and paint micrograms of this. And in six weeks, you're going to get tumors. It's a very striking phenomenon.

Q. Uh-huh.

A. I started playing with this 10:44 material in cell culture, and I had a cell

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culture that began to go back. That means it began to develop funny areas of transformation in it. And I put the TPA in it, and then all of a sudden it blossomed. And so I developed an assay system where I would put into a dish 100 known transform cells, cover it with a layer of normal cells, that would prevent the tumor cells from growing out.

Q. Uh-huh.

A. If I put the promoter in, the tumor cells would grow out, so the -- what the agricultural people had me do was use this assay to check for the tumor promoting activity of these condensates in my -- in my cell culture system.

Q. And what type of cell did you use?

A. These were mouse cells. The name of the cell was 3T3, and it was developed by Todaro and Green at New York University, where I was.

Q. Uh-huh.

A. And the transform cells were cells that were transformed by a virus called SV-40, which is a monkey virus that transformed to mouse cells, don't -- it worked. You know, it

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was --

Q. What was the cell type? What kind of cell was it?

A. These were fibroblasts, mouse fibroblasts.

Q. And the cell layer that you put on top was -- were normal fibroblasts?

A. Normal fibroblasts, right. And there was over a layer of 100 transform cells.

Q. Just out of curiosity, why the layer of normal cells above the transform cells?

A. Well --

Q. Because the transform cells were not reproducing, they were --

A. Yeah. They reproduced too. Everything reproduces. The reason is that it's sort of a -- it's sort of a model for a tumor. A tumor is a funny cell surrounded by a lot of normal cells. And the reason a tumor growth is that it escapes the controls. And what I was doing in this way was -- the promoter caused the tumor cell to escape the controls, and it was, you know, I thought, a good way to look at tumor promoters, and the

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TC who I worked for at the Department of Agriculture, wanted to add it to the database. There were now mouse skin painting studies, Fred Bock was doing sebaceous gland studies, Phil Thayer at ADL, where I later went, was doing cell toxicity studies, and I was going the tumor promotion studies. This whole battery was done on all of the -- I don't know how many -- I think we ultimately looked at 24 different tobacco varieties that they had played with, different -- different suckering agents, different fertilizing agents. The agriculture people were doing this.

Q. What substances -- if you kind of look at all that work, what substances jumped out as -- as primary promoters, primary --

A. For the promoting activity of the cigarette smoke condensate, most of them were like each other. Nothing really jumped out as being highly hot or active --

Q. Uh-huh.

A. -- from any of the situations. There were, you know, 20, 30 percent differences, but nothing doubled the activity,

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10:47 nothing that was big enough that you would stand up on the table and say, Wow, there's something in there that's hot.

Q. So there were a number of things

10:48 that showed -- tested positive as a promoter, but nothing that was --

A. They all -- it's interesting. They all showed positive as a promoter, which agreed with our mouse skin painting studies

10:48 that we had done earlier.

Q. Right.

A. But there were very few of them that were different from each other. There was a suggestion that with the alcohol

10:48 aliphatic suckering agents, there might have been a slight activity, so we went off -- we went off on that for a while and looked at suckering agents. And they were -- they were modest motors, they weren't very hot, but in

10:48 fact, they did give rise to an activity, the chemical did.

Q. And the alcohol suckering agents are something that was added to the tobacco?

A. No. No. This is something that

10:48 is used in the field to get rid of the lower

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leafs.

Q. Right.

A. How much of it ends up in the tobacco later and how much eventually gets transferred to the condensate, I don't know.

Q. Applied it to tobacco in the field --

A. In the field.

Q. -- to get it to drop the lower leaf?

A. That's right.

Q. A herbicide, I guess? How does it accomplish its purpose?

A. I don't know what the -- how it acts. I mean, it's specifically named a suckering agent, and it's used in the tobacco industry.

Q. And it ends up as a constituent of condensate?

A. I don't know. We never analyzed condensate for it. I'm not sure anybody ever did.

Q. The product delivered by a cigarette is smoke. Do you agree with that?

A. That's correct.

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10:50 Q. And smoke is this complex mixture of things that you and I have talked about already this morning, aerosol?

A. That's right.

10:50 Q. That is a mixture of, I think your comment was, almost anything you can name, correct?

A. Yeah. It's a mixture of particles and gases in an air stream.

10:50 Q. And the purpose of this product, smoke, is to deliver an adequate dose of nicotine to satisfy the user?

A. End of sentence?

Q. Period.

10:50 A. The purposes of the smoke is to satisfy user.

Q. Well, in -- and when you use "satisfaction," what do you mean?

A. Flavor, mouth feel, even the

10:51 social satisfaction of -- of smoking in a group of people.

Q. Uh-huh.

A. And nicotine, but nicotine is certainly not the only -- only reason that

10:51 people smoke.

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10:51

Q. Right. But -- but you've -- in your work in preparation for this case, have you ever seen a document or a heard cigarette discussed as a delivery mechanism for nicotine?

A. Not as part of this work, but I have in my history. You know, I think even -- even those in the general public were familiar with the R.J. Reynolds Premier.

10:52

Q. Would you agree with me that a cigarette, in effect, is a drug administration system for nicotine?

A. I think that nicotine is one of the exposures that one gets when one smokes.

10:52

Q. Do you believe that nicotine is addictive?

A. No.

Q. Have you -- are you familiar with the Brown & Williamson documents that -- that

10:53

refer to nicotine as an addictive substance?

A. I have not seen those.

Q. And it -- it is now my understanding you're being offered and as an expert on the subject of addiction?

10:53

A. I am certainly not an expert in

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10:53 that.

Q. And so you're -- your view that nicotine is not addictive is based on what?

A. Well, it's understanding what -- 10:53 sort of a scientific layman kind of understanding. Again, understanding people's behavior with respect to addictive drugs. I don't see anybody going out holding up people and stealing money to by a pack of 10:53 cigarettes. I mean, I don't see a lot of the behaviors associated with addiction for -- for smokers.

Q. But -- and that behavior, what you've described is -- is behavior that -- it 10:54 seems to me, is unrelated to, at least, the pharmacologic issue of how nicotine relates --

A. No. It's directly related. I mean, one of the things for drug addicts is they need more and more and more, so 10:54 therefore, they have to go -- if they don't have the money to buy it. My understanding is cigarette smokers sort of titrate themselves. You know, people don't become a half-a-pack-a-day smoker or one-pack-a-day 10:54 smoker, a two-pack-a-day smoker and 10 years

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down the road, they're smoking 10 packs a day. People remain sort of where they are as a half a pack or one-pack-a-day smoker for years and years and years. And that's -- flies directly in the face of addiction, which is tolerance where you need increasingly doses of material.

Q. And so for that reason, I guess, would it be fair to say your -- your opinion is that it is habit-forming, but not addictive?

A. Yes.

Q. And the distinction, or at least the distinction you pointed out is the tolerance issue and the need for an increasingly high dose to achieve some level of satisfaction?

A. Which is one -- that's one of the cardinal definitions of addiction.

Q. And earlier -- and let me ask you: Are you a smoker?

A. No, not anymore.

Q. Former smoker?

A. I smoked from the time I was 16 until February of 1963 when I caught one of

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10:55 the first Asian flus that came through this country, and I stopped smoking for two weeks and never started again.

Q. Did you try to quit before that?

10:56 A. No.

Q. Why did you start?

A. Who knows. You know, I was a 16-year-old, all my buddies smoked, so we all smoked.

10:56 Q. How did you get cigarettes when you were 16?

A. I went to the store and bought them. When I was 16, it was 1947 and they weren't carding people. You didn't have to

10:56 look 30 or older. If you had what I recall was 22 cents, you could by a pack of cigarettes in 1947.

Q. Times have changed.

Do you have children?

10:56 A. I have two boys, yes.

Q. Do they smoke?

A. No, they don't.

Q. If they came to you and said, Dad, I'm thinking about starting smoking, what

10:57 would you --

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10:57 A. I'll kick your ass around the block.

Q. Why?

A. Smoking -- the prevention -- if you could get people to stop smoking in this country, it would be the greatest public health benefit that would ever happen.

Q. And why is that?

A. That the incidence of lung cancer, cardiac disease, emphysema and chronic obstructive pulmonary bronchitis would fall dramatically.

Q. Which leads me to where I started next. And you had told me before that as a consultant, your view was if somebody wanted to know the truth, they could come to you and you'd tell them?

A. That's right.

Q. Do you believe that smoking causes lung cancer?

A. Absolutely.

Q. Do you believe that it causes emphysema?

A. Yes.

10:58 Q. Cancers of the head and neck?

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10:58 A. I'm not sure about that.
Q. COPD you already mentioned?
A. Yes.
Q. What about prenatal complications,
10:58 low birth weight babies?
A. I think the -- I think the
evidence for that is strong enough that I
would -- I would concur with that.
Q. Cardiovascular disease?
10:58 A. Yes.
Q. And when you talk about that the
evidence is strong enough, what are you
referring to?
A. Human evidence, epidemiology.
10:59 MR. THOMPSON: Why don't we
go off the record for a second. He needs to
switch.
THE VIDEOGRAPHER: We're off
the record.
11:00 (A recess was taken.)
THE VIDEOGRAPHER: We're back
on the record.
Q. (By Mr. Thompson) Doctor, we're
back after lunch. Before we went to lunch,
13:01 you told me you were going to tell the truth

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and you did. You told me that it was your belief or that you believed that smoking causes cancer and a number of other diseases that we talked about.

Would you agree with me that that's the prevailing view among members of the medical and scientific community?

A. I think that's certainly the prevailing view among public health officials and medical people.

Q. But in your opinion, it's not the prevailing view among members of the general scientific community?

A. Well, it's probably the prevailing view of most of my colleagues in the toxicology profession.

Q. So toxicologists, medical doctors, public health professionals, you would agree that the prevailing view among those categories of people is that smoking, indeed, causes these diseases?

A. Yes.

Q. And would you agree with me that that has been the prevailing view for decades?

A. For some time. I mean, it has

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13:02 increased in force and potency since the first surgeon general's report in 1964, but as the years go on, the evidence increases, so the confidence gets larger.

13:02 Q. The evidence has grown stronger and accumulated since 1964?

A. Yes, it has.

Q. Within the scientific community in terms of the toxicologic people who do the

13:02 work that you do, would you agree with me that they've accepted the relationship since the '60s?

A. I'm sorry.

Q. Since the '60s, since even before

13:03 the surgeon general's report.

A. What's your question?

Q. Would you agree with me that those people in your profession studying the cellular effects, toxicologists, have accepted

13:03 that even since before the surgeon general's report?

A. I don't think so. I think that over the years, I say, it's grown. The skepticism has decreased.

13:03 MR. THOMPSON: Let's go off

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:03 the record for a second.

THE VIDEOGRAPHER: We're off the record.

(Off the record.)

(Deposition Exhibit 1 was marked.)

THE VIDEOGRAPHER: Back on the record.

Q. (By Mr. Thompson) Doctor, you were at Arthur Little & Company back in '61 through '63, originally?

13:05

A. That's correct.

Q. Let me show you what I've marked as Exhibit 1, which is a report from Arthur D. Little, Inc., dated March 15th, 19 -- I'm sorry. I don't have another copy.

13:05

MR. McGAAN: I'll just look over his shoulder.

Q. (By Mr. Thompson) -- March 15th, 1961?

13:05

A. This preceded my joining Arthur D. Little.

Q. Okay. But at any rate, this is a company you went to work for and worked for a couple of years?

:05

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13:05 A. At that time, yeah.
Q. As a biologist?
A. As a biochemist.
Q. And here Arthur D. Little is saying, There are biologically active materials in cigarette tobacco. They are cancer causing, cancer promoting, poisonous, and basically stating those things without qualification, correct?
13:06 A. That's what this document says.
Q. Okay. And when you worked at Arthur D. Little in, I guess -- when did you go to work in 1961?
A. Pardon?
13:06 Q. When in 1961 did you go to work --
A. It was in the autumn. It was October.
Q. Okay. And you worked through --
A. I worked there for two years at that time.
13:06 Q. So throughout 1963?
A. '3, right, and then I left.
Q. When you were working there, was -- clearly, since your work involved cigarette smoke condensate, I assume you would

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13:06 have discussed -- no?

A. Not at that time.

Q. Okay. No discussion with your co-workers about cigarette smoking?

13:06 A. At that time, the L & M program was not widely discussed among the people in the life sciences group.

Q. Okay.

A. It was discussed to some degree at 13:06 staff meetings, but -- but it was pretty much the private province of my then boss, Charles Kensler, who was the sole -- pretty much the sole conduit.

Q. And was he -- how do you spell his name?

A. K-e-n-s-l-e-r, Charles.

Q. Was Mr. Kensler somebody who, in your opinion, was qualified to do the kind of work you were doing?

13:07 A. Eminently.

Q. And you respected him as a scientist?

A. I certainly did.

(Deposition Exhibit 2 was marked.)

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13:07 Q. Let me show you what I've marked as Exhibit 2.

A. I don't see any source of this document as to who signed it, who wrote it, whatever.

13:07 Q. Understood.

A. It's an anonymous document, as far as I'm concerned.

Q. But if he was in charge of the L & M project, at least one would assume he would have had some purview over the types of statements like this that were made as part of the project?

A. I would think so.

13:07 Q. Let me show you what I've marked as Exhibit 2. It's a working memorandum dated April 24th, 1963, from a Arthur D. Little, Inc., from Mr. Stefan Peter. Do you know Steve Peters?

13:08 A. I didn't know Steve at all.

Q. Okay.

A. I had heard of him. He was not in our group in life science. I'm not sure which group he was in. He may have been in statistics.

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Q. Well, if you'll -- if you'll look at the very first paragraph of the document, it talks about an argument to be presented by Arthur D. Little before the surgeon general's committee in the Littlefield case. Are you familiar at all with Arthur D. Little preparing a presentation for the surgeon general's committee?

A. I was aware that they worked very hard with Liggett & Meyers, and I know they sent the surgeon general loads of stuff. Kensler, as a matter of fact, was insistent that Liggett cooperate and be -- and be very forthcoming --

Q. Uh-huh.

A. -- which they were.

Q. In the second paragraph, could you read the first sentence of the second paragraph?

A. Uh-huh.

Q. Why don't you read it out loud.

A. Basically, this is from the memo of Stefan Peters of Arthur D. Little dated April 24th, 1963, and I'm reading from his memo.

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13:09 Q. Correct?

A. It says, Basically we accept the inference of a causal relationship between the chemical properties of ingested tobacco smoke and the development of carcinoma, which is suggested by the statistical association shown in the studies of Dall and Hill, and was with some reservations and qualifications, and even estimate by how much the incidence of cancer may probably be reduced if the carcinogenic matter can be diminished by an appropriate filter by a given percentage.

Q. And in the paragraph when it says "we," it appears to be Arthur D. Little in their presentation?

A. That would be my estimate.

Q. Okay. And so based on this document and authored by Stefan Peters, at least as early as 1963, Arthur D. Little, Inc., the company you worked for during that time period, was saying that they accepted the causal relationship between smoking and carcinoma?

A. Not the company. Scientific individuals within the company wrote opinions

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about their acceptance of the -- of the view about smoking, but I mean --

Q. It wasn't a company position?

A. Well, you have to understand that a company of consultants is like a company of lawyers.

Q. Everybody has -- everybody has their own --

A. I mean, everybody's got their own shop, they have their own clients. The company is sort of the resting place where we sit.

Q. Okay.

A. But the individual opinions are the opinions of the people, not of the company.

Q. Understood. Do you know whether or not that was the opinion that was expressed to the surgeon general's committee in 1963?

A. By ADL and Liggett Myers?

Q. Yes.

A. I don't know. I was not directly involved with the preparation of those materials. I was -- I was chasing cancer chemotherapy drugs at the time.

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13:11 Q. Understood. And earlier you testified, though, that at ADL it was your experience -- I guess a policy that you-all told the truth to your clients?

13:11 A. Yeah.

Q. And so if this is what Mr. Peters believed, then that is what he would have told his clients or anybody that asked him?

A. I think that's true.

13:11 Q. Would you agree with me that -- that cigarette companies like Liggett & Myers, like Brown & Williamson have known for decades about the relationship between smoking and lung cancer?

13:12 A. I can't answer that. I'm not an employee of those companies. I'm not even intimate of -- of the people of those companies. The only people who can answer that properly are the -- the people within the companies themselves.

Q. But one of the things you've been asked to do as part of your preparation for testimony in this case is review documents, internal documents, of Brown & Williamson that relates to their scientific research and

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development programs and their research?

A. Yeah. The documents I reviewed were almost all BATCo documents. There were a few Brown & Williamson, but they were almost -- like 99 percent of them were BATCo.

Q. In those documents, did you see any documents that indicated that Brown & Williamson or BATCo or any of the related companies discussed or acknowledged the causal relationship between smoking and lung cancer as early as the early 1960s?

A. I did not see anything about the causal relationship.

MR. THOMPSON: Unfortunately, I only have one copy of some of these.

Q. (By Mr. Thompson) As part of your disclosure, Doctor, there were a number of documents that you reference. Primarily, they were two sets of documents that -- that Scott Appleton produced as part of his deposition. One set was a set of company documents fairly voluminous. The other set was a smaller set that included some medical articles. Are you familiar with those reference documents?

A. Yes.

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(Deposition Exhibit 3 was marked.)

Q. Let me show you what I've marked as Exhibit 3, and then I -- there are a bunch of stickers on here because we're going to try and use the same documents over and over, but if I could get to you look at it and look at Page 29. I'd like to --

A. I have been handed the -- I suspect, an excerpt from a research conference Southampton 1962, Smoking and Health, Policy on Research, chairman Mr. A.D. McCormick, and I've been instructed to look at Page 29.

Q. And on Page 29, and actually in a number of places, I just marked Page 29, there was running discussion among representatives of the conference. And on Page 29, I think that it is -- sorry --

A. Yeah. Okay.

Q. Mr. Green that is urging the company to -- to acknowledge the causal link between cigarette smoking and cancer, and I just -- is this a document that -- it's part of the set of documents that you list as relying upon. I'm just curious as to whether

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or not you read that?

A. I'm pretty sure that I did if it were sent to me.

Q. Okay. And -- and would you agree with me that that's an indication that as early as 1962, they were openly discussing the possibility of -- of going ahead and acknowledging the causal relationship between smoking and lung cancer?

A. That's what the sentence says.

Q. And based on your review of the document -- documents in this case, the Brown & Williamson and BATCo documents, it is not your understanding that the company was aware of the causal connection as early as 1960?

A. I'm not sure what your question is.

Q. Well, I'd asked you before we looked at the document whether or not you would agree with me that the companies, including Brown & Williamson, was aware of this causal relationship as early as the '60s, and you said no?

A. I have a problem with that because companies can't be aware of anything. People

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13:16 in companies can be.

Q. Certainly.

A. But -- and individuals can be, but a company is, you know, an inanimate object.

13:16 Q. And I understand that, and so let me qualify that, that the individuals within the organization of which Brown & Williamson was a part, who attended the R & V conference at Southampton, were clearly and openly

13:17 discussing the causal relationship between lung cancer and smoking?

A. That is true. They were discussing the relationship.

Q. Well, let me ask you this,

13:18 Doctor. I talked to Scott Appleton a couple of weeks ago, and you know Mr. Appleton, correct?

A. I know of him. I've never met him.

13:18 Q. You've never met him? He's the smoking and health director for Brown & Williamson?

A. I'm not sure that's his title --

Q. Changed?

13:18 A. But he's director of safety --

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Q. Okay.

A. -- and health.

Q. Mr. Appleton told me when we talked -- when asked about the relationship between smoking and lung cancer, speaking on behalf of Brown & Williamson, that we just don't know. That was his -- his answer. I said, Does smoking cause lung cancer? He says, We just don't know.

A. I read his deposition and the statement. I'm not sure that's what he said.

Q. Okay. What is your -- if you read his deposition, what is your understanding of the position that he took?

A. My understanding of his position was that he acknowledged that there was a statistical association in human studies between smoking and lung cancer, but that for him as a scientist, that the body of evidence was not sufficiently strong for him to come to the conclusion that smoking caused lung cancer.

Q. And so in that respect, you disagree with Mr. Appleton?

A. I disagree with the conclusion

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13:19 that Mr. Appleton came to, yes.

Q. And -- and you understand Mr. Appleton was speaking not only as a scientist, but he was speaking -- he was 13:19 speaking on behalf of Brown & Williamson as part of that deposition?

A. You're making that assumption. I don't know that.

Q. Well, let's assume that he was. 13:19 Is that not an irresponsible position for a manufacturer of a product to take based on the information that is available?

A. The business of coming to a scientific conclusion is a very individual 13:20 matter. I frankly am very troubled by the fact that despite it's been -- the fact that it's been tried over and over again, no one has ever produced a bronchogenic carcinoma in an animal after a full lifetime of smoking at 13:20 doses that far exceed human exposures. That's troublesome to me as a toxicologist. And I can see that some toxicologists or risk assessment people might say, This is a serious flaw in the total body of information, and 13:20 because of that, I am not prepared to accept

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13:20 1 the final conclusion that smoking causes
2 cancer.
3 Q. And so --
4 A. I don't agree with that, but I
13:20 5 don't disagree with someone taking that
6 argument.
7 Q. And -- and why is that a
8 justifiable position in your opinion?
9 A. The business of dealing with
13:21 10 smoking as a public health matter and dealing
11 with the problem of smoking causing lung
12 cancer as a scientifically provable item are
13 two very different things. There are very
14 different levels of knowledge and
13:21 15 understanding that people need to do that. If
16 one does not -- if one can't reproduce this in
17 an animal and if one doesn't know the
18 mechanism of how it's done, those are serious
19 questions to some people that -- that may
13:21 20 prevent them from coming to a conclusion.
21 Q. And so in talking -- in the
22 context of pure science, looking for
23 scientific certainty, you're saying that that
24 is a valid position to take?
13:21 25 A. If one is looking sort of for

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13:21 proof in sort of a scientific logic kind of essential, the absence of two very critical pieces of information may allow some scientists to come to the conclusion that it
13:22 has not been proved from a scientific point of view.

Q. Right.

A. That did not deter the surgeon general in 1964. I mean, we didn't know
13:22 anywhere near as much data, but on a public health matter, he said, Based on what I know now, smoking is not good for you.

Q. And --

A. And even he acknowledged in later
13:22 reports that there were problems of the animal studies that they had never shown problems.

Q. But you would agree with me, in effect, we agreed earlier that the epidemiologic proof just gets stronger and
13:22 stronger?

A. Yes. I -- you know, from my point of view, and again, maybe I've been bumming around with epidemiologists too long, but I think that in 1997, unlike back in the '60s
13:22 and '70s when epidemiology was not nearly as

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strong a science, I think it's appropriate to make a causal inference from strong epidemiological data. That was not the view back in the '60s and '70s by a long shot.

Q. But as you and I discussed earlier, when we were talking about products or chemicals for that matter, that are going to be either placed in the environment or, more significantly, directed towards a human being, we're not dealing with pure science anymore? We're dealing with the kinds of balancing that you talked about earlier, correct?

A. That's correct. Yeah.

Q. And that is to say that this is a question of pure science ignores the fact that we're talking about a product that is sold to and consumed by literally millions of people around the world?

A. But from the regulatory point of view, you're talking about a very different item. What the EPA regulates against or for are exposures that you have no control over, and that's why the EPA regulations on pesticides, air pollutants and other materials

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are so strong.

Smoking is a matter of personal choice. It's not a matter of unchosen exposure. An unchosen exposure is the driving force behind the regulatory view that one needs this body of information to protect people.

Q. What about drugs? I mean --

A. What do you mean drugs?

Q. There is an element in choice?

A. In pharmaceuticals, you mean?

Q. Yes.

A. Yeah. There is a -- there the element of choice is a very gray area. You know, if you have high blood pressure and you want to lower it, there isn't much of a choice, but yet there is a choice.

Q. You either take the drug or you don't?

A. Or you don't.

Q. But even with the element of choice, the regulators have stepped in and said, We are going to do -- we are going to weigh the evidence --

A. Yeah.

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13:25 Q. -- because human beings are involved?

A. That's right. And, again, the matter of choice is a pretty academic question. If you're sitting here with a blood pressure of 220 over 180 and the doc comes up to you and says, you're going to die in six months if you don't take this medicine. You can choose not to take it, but there's not a one of us on the face of the earth that would not take that medicine. So it's a -- it's a very different kind of exposure situation.

Q. Well, and if we -- if we address the question of causality of, you know, causation between an exposure and a disease, I guess your argument is that really is the realm of science and pure science?

A. Yes.

Q. But what if -- what if we address the more basic question of a company's responsibility to a consuming public? If I ask you the question, you know, is cigarette -- is a cigarette a product? The -- and we agreed earlier that the product really is smoke -- is the product that is being sold

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13:26 safe? In your opinion, is the product that is being sold in a cigarette safe?

A. No.

Q. And -- and when I asked that question of Dr. Appleton again, his question was, We don't know. And my question to you, Doctor, since we're talking about physicians and viabilities, is that not an irresponsible position for a manufacturer and seller of a product to take?

13:27

A. Step back into the history of things. There's not a soul on the face of this planet that does not know that cigarette smoking is not good for you, not a soul. This -- so this back and forth is pretty academic. I mean, it's not -- the cigarette packs are labeled. They've been labeled for over two decades, that -- that smoking can cause cancer, that smoking can give you emphysema, that smoking can cause high blood pressure. I mean, it's been on the pack there for over two decades, so the business of arguing about whether a manufacturer should determine whether it's safe or not in 1997 seems a pretty abstruse point. I mean, the

13:27

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13:28 public was warned over 20 years ago.

Q. You testified earlier that you started smoking when you were 16.

A. Right.

13:28 Q. With all the knowledge that you've just -- and I'm assuming that what you're telling me is at 16 years old, you were fully aware of all the dangers of smoking?

A. I was 16 in 1947.

13:28 Q. Okay.

A. I don't think anybody really was aware or cared. It was right after the first World War -- or second World War. The social climate was such, you know, people really

13:28 didn't start asking questions about that until much later.

Q. Do you think 16-year-olds today understand all the implications of beginning a smoking habit?

13:29 A. I really don't know. My kids never started, although, my wife at that time did smoke occasionally, but my kids never started, and I assumed that they had plenty of opportunity to, and I -- I never really talked

13:29 to them about why they didn't when they were

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13:29 teenagers. Teenagers are very well-informed these days.

It's my guess, and it's only that, that a teenager probably does understand that smoking is not good for them. Why they start and continue, I think that's more of a social problem than -- than -- than a medical or a scientific one.

Q. Do you -- if it is reasonable, if it is a valid position for Scott Appleton to take as a scientist that, I don't know, it has not been proven to certainty, and, therefore, We don't know, why is it not reasonable to view this supposed smoke of choice as whether it be a 16-year-old or a 35-year-old as taking Scott Appleton or Brown & Williamson and their position at their word?

A. I don't know. You'd have to talk to those people. Do they take the cigarette companies at their word, that they don't know whether it's harmful or not? I don't -- I don't -- you know, it's a supposition that I don't have an answer to without talking to people.

Q. But would you agree with me that

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13:31 if on one hand you're saying it's a reasonable position to take on behalf of the cigarette company that it is -- how could it be an unreasonable position or belief on behalf of the consuming public that they can rely upon that position?

A. I don't know that that position has been highly broadcast or purveyed to the public with great intensity. I'm not aware of it. You know, I don't see any ads that say, We don't know about the safety of our product. I have never seen an ad like that in my life in the cigarette business.

Q. The ads just say, Smoke Kool and relax and feel good.

A. That's a different -- that's a completely different thing.

MR. McGAAN: In fairness, the Kool ads don't say that.

MR. THOMPSON: I made that up.

MR. McGAAN: I know.

A. I came from a generation when you undoubtedly have the ads in your file when doctors used to testify that smoking was not

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bad for you when I smoked cigarettes, which, you know, with present day knowledge is pretty appalling.

Q. (By Mr. Thompson) No comment.

(Deposition Exhibit 4 was marked.)

Q. Let me show you what I've marked as Exhibit 4, speaking of ads.

MR. McGAAN: This is off the record.

(Off-the-record discussion.)

MR. THOMPSON: We're back on.

THE VIDEOGRAPHER: Back on the record.

Q. (By Mr. Thompson) Have you seen Exhibit 4 before?

A. No, I haven't.

Q. Take a look at it because it's actually --

A. What is the date of this?

Q. I believe it was 19 --

MR. THOMPSON: And you can correct me, Counsel, if I'm wrong.

Q. (By Mr. Thompson) Was it 1952?

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A. '4.

MR. McGAAN: '4.

MR. THOMPSON: Thank you.

MR. McGAAN: Can you read your copy?

13:33

THE WITNESS: I can manage.

Q. (By Mr. Thompson) This one might be better, not much. Try that.

MR. McGAAN: I can read it.

13:35

THE VIDEOGRAPHER: We're off the record.

(Off-the-record discussion.)

THE VIDEOGRAPHER: We're back on the record.

13:36

Q. (By Mr. Thompson) Doctor, have you had a chance to look through Exhibit 4?

A. Yes.

Q. The -- there's a -- on the left-hand column, the -- not the last sentence, but the two sentences beginning with, We accept an interest in --

13:36

A. Right.

Q. -- the public. Can you read those two sentences for me?

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13:36 A. Yeah. It says, We accept an interest in people's health as a basic responsibility paramount to every other consideration in our business. We believe the
13:37 products we make are not injurious to health.

Q. Whether or not you agree that a company has -- that makes a product just has a responsibility to the consuming public, would you agree that in making this statement
13:37 publicly and to the consuming public, that the companies, in effect, have taken on the responsibility and represented that the health interests of the consumers are paramount to the companies?

13:37 A. That's what that sentence says.

Q. And so --

A. Although --

Q. Go ahead.

A. I note that this doesn't include -- matter of fact, it doesn't include Liggett Myers.

Q. But it does include Brown & Williamson?

A. It does include Brown & Williamson.

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MR. McGAAN: Now, there's a name cut off in the middle row at the bottom.

MR. THOMPSON: I cannot remember who that is.

MR. McGAAN: I can't remember.

THE WITNESS: I can't make it out. It's not Liggett Myers.

MR. THOMPSON: Lorillard, I think.

MR. McGAAN: No, they're just above it.

MR. THOMPSON: Oh, they're just above it. I don't know. I'd have to --

MR. McGAAN: I don't know. It's not important.

Q. (By Mr. Thompson) Is continuing to manufacture and sell a product that very well may cause lung cancer, emphysema, the things that you and I have discussed, consistent with the position stated in this document?

A. This document was written in 1954. And in 1954, based on the information that was available, it's a supportable

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13:39 document. And in 1954, the tobacco industry research committees said that we believe that the product we make are not injurious to health, in 1954.

13:39 Q. Uh-huh. But in saying that we assume the responsibility or that the interest in people's health, we accept an interest in people's health as a basic responsibility paramount to every other consideration in our 13:39 business, from that, would you not at least infer that at some point if the evidence changes that the companies would change their position, change their conduct?

A. Which? Position or conduct?

13:40 Q. Well, let's start with position, on whether or not smoking causes disease.

A. Well, I -- you know, at least from reading the BATCo stuff, they did. The BATCo, as time went on, openly accepted the 13:40 statistical association of lung cancer with -- with cigarette smoking, but they raised questions, as Scott Appleton did, about the proof of the situation from a scientific point of view.

13:40 Q. And how about the second in the

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:40 continuing to sell a product in the face of evidence that is continuing to grow decade after decade?

A. They sell a product that is 13:40 consumed by choice. One could say the same thing about alcohol. Matter of fact, one could say the same thing about automobiles. Automobiles kill and maim an awful lot of people in this country. And I'm sure there 13:41 are other examples of products sold that cause damage, lawn mowers, hedge clippers cutting off fingers.

Q. So, in your opinion, continuing to sell a product that kills or maims is not an 13:41 irresponsible act?

A. Continuing to sell a product that they do, which is a product that is bought and consumed by choice, is not irresponsible.

Q. We also talked about addiction, 13:42 and I asked you whether you thought cigarette smoking was addictive or nicotine was addictive, and your answer was no. In your review of the BATCo documents, did you come across documents where scientists in that :42 organization as early as the early '60s

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13:42 discussed the addictive nature of nicotine?

A. I think they discussed a lot about the pharmacology of nicotine. I don't recall a lot being talked about addiction.

13:43 Q. And -- and one of the things that you and I have been talking about in the last few minutes, and it's important, I think, to the point that you've made, is this element of choice. Would you agree with me that somebody

13:43 who is a -- addicted to a substance is not in a position to make the kinds of choices that you're talking about?

A. There are hundreds of thousands of people in this country who have stopped

13:43 smoking. There are some who find it very difficult to stop, but there are hundreds of thousands, if not millions of people in this country, who have stopped smoking, which tells me that people can stop if they want to, and

13:43 that the habituation or attraction of what nicotine is that grabs people can be overcome with appropriate help and -- and counseling.

Q. Sure. But -- but that's true of, you know, of other more traditional drugs, I

13:44 mean, not traditional, but let's say illegal

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drugs.

A. Yeah.

Q. But heroin?

A. There we're talking about, I think, orders of magnitude difference in the nature of a problem with respect to the kind of withdrawal and the kind of hold that a chemical has on a person.

Q. But -- and I understand your position on that, but would you agree with me that if a person is addicted to a substance, that that, at the very least, limits their ability to make choices?

A. On a generic basis, yes. If a person is addicted to a substance, it limits their ability.

Q. Let me refer you back to Exhibit 3 on Page 4, and I'll represent to you, so you don't have to flip through it, you've already looked at it, these are some of the initial statements by Sir Ellis at the Southampton conference, and if you'd -- could you read the sentence that I highlighted, please?

A. Yeah. It says, Lastly, smoking is a habit of addiction that is pleasurable.

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Q. 1962, and Sir Ellis -- from your review of the documents, who is Sir Ellis?

A. Sir Ellis was the -- the head of BAT.

Q. And he was -- and he not only was the head in a sense of a business, he had -- he was very much involved in the -- in the R and D aspects of the companies?

A. That's true.

(Deposition Exhibit 5 was marked.)

Q. Let me show you what I'll mark as Exhibit 5. It's a document dated July 17th, 1963. You might want look at it first. I've tabbed -- the pink tab, if you'll look, once you get a chance to look at the document.

A. You want me to look at the pink tab at that?

Q. Yes.

A. Would you please identify the document for me?

Q. It's a memorandum, internal memorandum, discussing several projects that were done at BATCo in the '60s.

MR. McGAAN: Can we go off

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the record for a minute?

MR. THOMPSON: Sure.

THE VIDEOGRAPHER: We're off the record.

(Off-the-record discussion.)

THE VIDEOGRAPHER: We're back on the record.

Q. (By Mr. Thompson) Doctor, we've been talking about nicotine and the question of addiction. I've handed you what I've marked as Exhibit 5, and what I would like you to do is simply identify the document by the date and the title of the document, please, on the record.

A. The document reads, Strictly private and confidential, Implications of Patel Hippo 1 and 2, and the Griffith filter, and it's dated July 17th, 1963.

Q. And in formulating your opinions, the opinions that you've stated today, and we've discussed regarding whether cigarette smoking and nicotine, in particular, is addictive, you've been asked to review Brown & Williamson and BATCo documents; is that

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13:49 correct?

A. That's correct.

Q. Was this one of the documents that you were provided to review in preparation for your testimony?

13:49 A. No. I've never seen this document.

MR. McGAAN: And let me make -- just make a statement for the record to clarify. The disclosure of the summary of opinions of Dr. Sivak made in this case should make clear that we have not offered Dr. Sivak as an expert in addiction. We offer opinions on addiction.

13:49 MR. THOMPSON: Understood.

Do you want to mark that and have her seal that?

MR. McGAAN: No. My position is that it doesn't need to be sealed, though, 13:49 privilege has been stolen from the company and disseminated publicly in a wrongful fashion, but nonetheless, it's public.

MR. THOMPSON: Understood.

Are we still on? I've lost 13:50 track.

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(Deposition Exhibit 6 was marked.)

Q. (By Mr. Thompson) Let me show you what I've marked as Exhibit 6, Doctor. The document -- Exhibit 6 is some notes from the BAT R and D conference in Montreal in 1967.

If you'll look at Page 3, there are a list of assumptions at the bottom.

A. Ah, yes.

Q. And under subheading small b, would you read that for me, please, Doctor?

A. There is a minimum necessary level of nicotine. Smoking is a habit attributable to nicotine. The form of nicotine affects the rate of absorption by the smoker.

Q. In -- again, in the context of our discussion about choice and addiction, is this one of the documents that you've reviewed --

A. Yes.

Q. -- regarding the history --

A. This document was provided to me.

Q. Okay. And in your opinion, the reference to smoking is a habit attributable to nicotine, and the reference to a minimum level -- necessary level of nicotine, that

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13:51 does not, at least, infer an understanding of the addictive nature of the nicotine?

A. Not at all.

MR. THOMPSON: Why don't we

13:52 go off the record and take a quick break.

THE VIDEOGRAPHER: We're off the record.

(A recess was taken.)

THE VIDEOGRAPHER: We're back

14:01 on the record.

Q. (By Mr. Thompson) Doctor, in preparation for your testimony today, it's my understanding that you've been asked to review, I guess, a collection of internal

14:01 documents from BATCo and Brown & Williamson relating to their research efforts; is that correct?

A. That's correct.

Q. Can you, I guess, describe for me

14:01 generally what you've reviewed and -- and the nature of the documents you've reviewed?

A. The great majority of what I've reviewed were reports of investigative laboratory efforts that were either sponsored

14:02 by BATCo at outside laboratories, like

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Document from the UCSF Library, http://www.industrydocuments.ucsf.edu/docs/rsjl0001

14:02 Battelle, LSR, or done internally in their own laboratories. I expect -- and I'm only guessing at this -- maybe something like 10 percent or less of the documents were 14:02 documents like these that were conference reports, research strategy meeting reports over -- over more than a 20-year period.

Q. Most of them, then, pertained to specific studies or --

14:02 A. The great majority of them were individual reports of -- of studies or sets of studies that were done. They were scientific reports.

Q. Uh-huh. You state in -- summary 14:02 of your opinion states that it is your opinion that BATCo pursued an extremely large and well-conducted biological research program. What leads you to that conclusion?

A. Well, I saw just in passing some 14:03 of the budget numbers, and the kinds of numbers that they were talking about were hundreds and hundreds of millions of pounds a year, which at that time, you know, a pound was five bucks, which meant that was a very 14:03 big program.

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Again, from -- from the L & M work that we did at -- at Arthur D. Little, I know how much, because we were their biological testing lab, and I know what the size of that program was, and it was only a tiny, tiny fraction of what the -- what the BAT program was.

Q. Now, BAT --

A. Or BATCo program.

Q. BATCo. BATCo was the largest manufacturer and seller of cigarettes in the world at the time; is that correct?

A. I don't know that.

Q. Do you have any -- any understanding of the relative size of the organization as a whole between BATCo and, for example, L & M --

A. I don't know that.

Q. -- or Lorillard? And so in saying "extremely large," you're focusing on the budget number primarily?

A. The budget number and, again, the numbers and types of studies that were done. I mean, a lot of the studies they did were very -- very significant large studies. To do

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14:04 the amount of skin painting experiment with eight or 10 variable in it at 100 or more mice per set. That is a big study all by itself, and they used to do a couple of those at a time.

Q. What percentage of the work that you saw in the documents you reviewed was internal work?

A. I don't know. This is just a guess, but my guess is --

Q. I understand.

A. -- the majority of it that I saw was outside contract work. How that fractioned out, I -- I really would have to go back and look very hard at that.

Q. Okay.

A. Because I didn't really make a good -- I just sort of took them as they come and read through them.

Q. And the outside contract work, was it in conjunction with the trade organization?

A. No.

Q. It was --

A. It was individually contracted by BATCo to these various outside toxicology and

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consulting laboratories.

Q. Okay. What was -- if the majority was outside work, was there a distinction in the type of work that tended to be contracted out?

A. No, there wasn't, because they did -- you know, they did mouse skinning -- painting stuff in-house and out. They did triangual (phonetic) stuff inside and out. They did inhalation work inside and out. I mean, I don't recall that there being in favoritism with respect to the -- to the kind of work that they put out, and -- and that they did in-house.

Q. And in your opinion, the work was closely monitored, competent --

A. Yeah. Yeah. It was very closely monitored, and -- and again, a lot of their work was done by Battelle Frankfort. And, you know, I guess, next to ADL, I would put Battelle Frankfort pretty much at the top of the list as a -- as a consulting laboratory where if I had work to do I would sent it. They're extremely responsible, good scientists.

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Q. From your review of the documents, were you able to gain, at least, a basic understanding of the structure of the R and D effort organization?

A. Not of the organization.

Q. Uh-huh.

A. I have -- you know, it was more an idea of were they -- you know, what they were trying to do. As -- as the program evolved over the years, I -- I don't really have a -- a good feel for sort of the box structure of who reported to who or who was responsible, even for initiating the studies.

Q. Right. What about the flow of information? Were you able to determine that the studies, for example, that you reviewed, the reports of the studies were distributed to subsidiaries or -- or to the general public?

A. I don't know that. I don't know that. Again, because they did have regular R and D conferences, they had a bioassay committee that met that included all of BATCo's pieces, it's my guess, and it's only that, that all of the information that was available to BATCo was available to BATCo

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Germany, BATCo Canada, Brown & Williamson.

Q. Did you ever -- well, let me ask you this: In your opinion, would it be, within a scientific research organization, appropriate for the legal department to get involved in deciding where information went, who had access to information?

A. Yeah.

Q. Within the scientific departments?

A. Well, you know, when information like that is developed, it may have legal consequences.

Q. Okay.

A. And I don't see anything wrong with -- with the legal department having an input into -- into distribution or fate of a document, even a scientific document.

Q. Did you see any evidence in the documents you reviewed of -- of the legal department limiting access or -- or limiting the flow of information within the company?

A. Not at all. As a matter of fact, some of these research and develop conference reports, they spent a fair amount of time in

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ways to improve the flow of information, developing a computer system, meetings more often. They were very concerned about making sure that -- that all of the pieces of BATCo and BAT got the information, and there's good documentation for that in a lot of those reports.

Q. Okay. Are you aware whether at any time as things progressed that -- that procedures changed and access to the information was limited by the legal department?

A. No. I don't know anything about that.

Q. You state that the purpose of the program generally was to identify and develop a commercially acceptable cigarette of lower biological activity as measured by prevailing virus?

A. Yeah. Well, that's written every year. I mean, I -- you just read their reports every year, and that's what they said they were trying to do, and I believe that's -- that, in fact, was the case, because that was -- that was the philosophy at Liggett

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as well.

Q. You state that despite all these efforts, ultimately, they failed to do so?

A. Yeah. They -- every once in a while, you found something with a little bit lower activity. Very often, those things were not acceptable, like --

Q. Go ahead.

A. -- like the Premier. They come up with this nicotine delivery device and no one would smoke it because it was so bad tasting. Again, we had the same experience with Lark cigarette, put a charcoal filter in, there was an improvement. We blocked the ciliastatic materials in cigarettes. It was an improvement to smoke that cigarette, but for some reason or other, we could never convince the people at L & M to make the flavor so there was an acceptable cigarette to smoke.

Q. And so acceptable, when we say "acceptable," we're saying people got to buy it?

A. They've got to buy it and use it, right.

Q. And acceptable really means

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14:11

commercially feasible, I guess?

A. Yeah. Yeah. That -- that -- what it means is that that total experience that smokers feel when they smoke has to be satisfied and has to be not unpleasant.

Q. Uh-huh. The -- the purpose is kind of a two-step as stated. It's a two-step process. Create a product with lower biological activity that is acceptable?

14:11

A. Acceptable.

Q. Looking at only the first piece of that puzzle, based on what you saw, were they able to create products with lower biological activity?

14:12

A. They were able to do things that did lower biological activities. As a matter of fact, you know, one of the classic ones is that as you make the cigarette skinnier, the amount of skin painting activity goes down.

14:12

You know, a fat cigarette, for reasons, I guess, of combustion products and things, skinny cigarette is less active on the back of a mouse.

The expanded sheets in some of the

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blown up tobacco products were less active

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than whole tobacco, and just the tobacco mixture, just the mixture between Burley and Virginia, the proportion of that would determine what the activity was on the back of a mouse, so, yeah, there -- there were changes in activity, but the key issue is, could they get one of significantly reduced activity that people would smoke, and they were never able to do that.

Q. In your review of the documents and the studies, did you find anything that -- that indicated that Brown & Williamson had unique knowledge about their product or BATCo had unique knowledge about their products that wasn't available to the consuming public or the scientific community at large?

A. No. They were not in the forefront of science. I mean, when they started doing skin painting studies, it had already been known for 10 years that cigarette smoke condensate gives rise to mouse skin tumors, and their only reason for using this was to try to monitor to see whether they could change the product to get a -- get a less active one. And they, you know, they --

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14:14 I didn't read anything that was -- as I indicated there, that was forefront enough that they would have even allowed them to publish anything.

14:14 Q. Was there -- so in your opinion, there was no significant information that BATCo, B & W had access to that they did not share -- that would have been new information that they didn't share with the scientific community?

A. No. I didn't see anything there that at the time it was done was not already known by a matter of many years in most cases in the scientific community.

14:15 Q. In this area during the time frame that we're talking about, I know that it was a number of years, what -- what types of things -- where was the path-breaking, ground-breaking work being done?

14:15 A. Well, the original skin painting work, of course, was done by Wynder in the early '50s, and then later on, Fred Bock, and Van Duuren and ourselves did it. And then after that, the -- the safer cigarette group, again, ended up being the major -- the major

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carrier of that. I mean, they had an enormous program of skin painting.

MR. McGAAN: Just to clarify, you referred -- I'm sorry -- to the safer cigarette group. What is that?

THE WITNESS: This is the NCI group under Gio Gori that was set up, I guess, and ran through much of the '60s and early '70s, and they had an enormous bioassay program, again, that I played a small part in. But they did 30 skin painting assays a year, looking at every possible combination with the same goal. And, again, after -- after five years and many, many millions of dollars, came up empty-handed.

Then the move went away from skin painting to inhalation research, and by the time that inhalation research started, it was already recognized from a couple of long-term studies that no one was able to get tumors. So BATCo took the position that, let's look at the short-term. Let's do a three-month study, look for pulmonary physiology, changes in lung structure as a measure of a reduction of activity because, you know, we could spend

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$2 million and run rats for two years, but we're never going to find any tumors.

Q. Right.

A. And then they did a couple of experiments, promotion experiments, where they did hamsters, gave them nitrosamine to initiate, and then gave cigarette smoke after that. And that just repeated stuff that Huffman and Wynder did.

14:17

Q. Uh-huh.

A. And, indeed, the cigarette smoke acted like a promoter. I mean, they just repeated the stuff that Wynder and Huffman found.

14:17

Q. Now --

A. And then they went into the short-term test area, mostly Aims assays.

Q. At some point along the way, they stopped doing mouse painting?

14:17

A. Yeah. I guess it was early '70s, maybe, when the last skin painting study was done by them.

Q. In your opinion, are there inherent problems with inhalation studies in animal models for this inquiry? Are there

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things that were discovered that suggested it -- it's never going to work?

A. The technology -- I mean, inhalation toxicology is a very complicated -- I mean, painting the backs of mice is a piece of cake. I mean, you stand there with a pipe and you skirt the backs of mice and you throw them back in their cage.

Inhalation toxicology requires engineers, particle people, exposure to devices, restraining devices, and considerations about dose.

Q. Uh-huh.

A. And dose, unlike when you give a pellet to a dog or a mouse or put 100 micrograms of tar on the back of a mouse, dose is a function of how much the rat is going to inhale, so that getting dose even in an inhalation experiment is a terribly difficult factor, be it cigarette smoke or anything, no matter what you're talking about in inhalation experiments.

Q. Throughout the years, really throughout the decades, this work was discussed internally as an attempt to find a

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14:19

safer cigarette, correct?

A. They used those words. They said a cigarette with reduced biological activity.

Q. But, I mean, I think that, again, and I just -- let me show you Exhibit 3 as an example, Page 26, discussions as early as 1962 using the word "safe." And I don't want to beg the question, but -- and the point is, in your opinion, lower biological activity would, in fact, create a safer cigarette, correct?

14:19

14:20

A. Lower biologic activity might.

Q. That would be the goal?

A. That would be the goal. There -- there would be some reason to expect that that's the case, but there certainly would be no assurance.

14:20

Q. In fact, let me show you what I'll mark as Exhibit 7. I ask you to look at Page 9. If you could identify the document for us, that would be helpful.

14:20

A. This is a research conference held at Kronberg 2, June, 1969, BATCo document.

Q. In fact, there they discuss what they think would be the safest cigarette?

14:21

A. Yeah.

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14:21 Q. And later on the page, in fact, there's a comment, it was at the same meeting that they decided to ban the Ariel project?

A. Right.

14:21 Q. And Ariel was a -- I guess, a Premier-like project that was, in effect, just a nicotine delivery system; is that correct?

A. I -- I only knew about Ariel from what I read about it in these reports, which

14:21 was very, very sketchy. I didn't have any idea of what the configuration of it was or anything else, and -- and so I don't know the details of it, but, yes, it was a tobaccoless nicotine delivery system.

14:21 Q. In effect, it was some sort of a tube that was heated that created an aerosol that had nicotine and something to give it --

A. Flavor.

Q. -- flavor?

14:22 A. Yeah.

Q. And the point was to deliver the nicotine without delivering any of the incomplete products of combustion, the tar?

A. Yeah.

14:22 Q. Do you recall seeing -- on what

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we're talking about, the purpose of the project being to create a cigarette that is truly lower in biologic activity. Do you recall references in the documents to -- to gimmick products that would, in effect, try and take advantage of the health concerns in a marketing sense without delivering lower biologic activity?

A. I never -- I don't recall anything like that.

Q. In your opinion, would that be something that -- that would be inappropriate?

A. I'm not sure what you mean.

Q. Well, I mean, to -- to create a -- a product that is designed to play to people's health concerns knowing that it, in fact, doesn't deliver anything that is truly safer, is misrepresentation, isn't it?

A. I don't think any cigarette company could or would be allowed to do that.

Q. Let me refer you, again, to Exhibit 3, and if you'll look at Page 29, and then onto Page -- I'm sorry -- 30. It's actually the same statement of Mr. Green where you had referred to earlier where he said --

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14:24 suggested that the company acknowledge the causal relationship between smoking and cancer, and then he begins to discuss some levels of work that ought -- he believed they ought to do. And right at the bottom, he talks about the second level. I think he calls it -- literally, he calls it a gimmick. And, in fact, throughout the documents, isn't is it true that -- that there are references to in discussions of using the health concerns and the health issue in a commercially advantageous sense, to try and use it as a marketing plus?

A. Well, I think that issue was raised, and I -- I'm not sure what he really means there in that number one thing. I -- gimmick level. I -- I just -- that -- that next sentence afterward is -- is pretty vague and abstruse, and I just can't make heads or tails of it.

Q. But at any rate, the concept of creating a cigarette that just purports that -- that plays to health concerns but doesn't really address any in your opinion would be inappropriate?

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A. Like I said, you know, I -- I don't think they would do it or even could do it. Even a company as aggressive as R.J. Reynolds with everything they did never -- never implied that Premier was a safer cigarette.

Q. Well -- and there's a reason for that, I mean, isn't there, Doctor, that that implication could be seen as a tacit acknowledgment --

A. That the other ones are dangerous.

Q. -- that the other ones are unsafe?

A. Possibly.

Q. In fact, if you'll look at Page 31 of Exhibit 3, Mr. --

A. McCormick.

Q. -- McCormick specifically states that that's the problem.

(Deposition Exhibit 8 was marked.)

Q. Let me ask you to look at what I've marked as Exhibit 8, which is the minutes from the 1968 research conference at Hilton Head, and -- and on Page 2, Item 5, which I've highlighted, and if you'll look at the

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14:28 description of the distinction between the health image cigarette and a health-oriented cigarette, it sounds to me like that's the gimmick we're talking about.

14:28 A. Well, I think these are.

MR. McGAAN: Please identify it for the record, please.

A. Yeah. This is research conference held at Hilton Head, South Carolina, 24 to 30, 14:28 September, 1968. It's a BATCo document.

Q. (By Mr. Thompson) And doesn't that sound like what we're talking about?

A. Well, you know, this is the discussion among people at a research 14:28 conference of certain possibilities.

Q. Sure.

A. It's a balloon that they -- that that was being floated. Whether or not they would ever go about and actually do that, one 14:28 has no way of knowing, but -- but research conferences are generally supposed to be open-ended conferences where all things can be discussed.

Q. Sure.

14:29 A. But I think the fact that they

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mentioned there by no means implies that they could -- or would do it commercially.

Q. On Page 39, the first highlighted sentence, would you read that sentence for me, out loud, if you would?

A. It says, On the question of how to sell a gimmick, certainly on the Canadian market, you stated what you thought people wanted to be told, and you made money by doing so. I don't have the foggiest idea what that implies.

Q. But at any rate, this is not a marketing conference --

A. Yeah, right.

Q. -- this is a research conference?

A. But without knowing what was said here, I can't make any comment on that.

Q. I understand. Throughout the documents, were you -- did you come across discussions of using the joint research efforts and in Britain -- forgive me if I forget the name of the organization. It's an acronym. Well, do you recall --

A. BIBRA.

Q. Excuse me?

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A. BIBRA?

Q. No.

A. Because I did some work at Britain Institute for Biological Research.

Q. Well, do you recall discussions about joint research and the importance of doing things as an industry as opposed to doing things as an individual company?

A. Well, yeah. In the early days, especially when Harrogate was being set up, they supplied money. As a matter of fact, my recollection was that they -- they sent their bioassay data, you know, off -- off to the Centralized Tobacco Research Unit in the UK.

Q. But wasn't the stated purpose of this joint research -- the agreement to share information, in effect, to avoid competition on the health issue?

A. I don't think so.

MR. McGAAN: Just as a point of clarification, did your question -- you're referring to the United Kingdom Tobacco Industry or something?

MR. THOMPSON: Yes.

Q. (By Mr. Thompson) If you'll look

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at Page 43 on Exhibit 3, the bottom. And again, Mr. McCormick speaking, I believe.

A. All right.

Q. Would you read that, please?

A. Mr. McCormick said, This was the situation which worried us all, that of the road company which sought to take commercial advantage of anything they happen to find. This was the whole reason why the UK, the manufacturers had set themselves up in a way that they had through TMSC. All information was pooled, and it really did work.

Q. And indeed, there were -- and TMSC is the acronym I was trying -- I was struggling for. In fact, there was some discussion of trying to achieve the same kind of relationship in the United States. Do you recall any of that?

A. Not specifically.

Q. On Page 44 of this same document, Dr. Griffith states that -- that in the UK, we already had a concentrated, coordinated effort and a similar approach, and states, could be of considerable value.

In fact, they -- they discuss on

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Page 42 a phenol crisis. Do you remember what the phenol crisis was about, the bottom of the page.

A. Yeah. Yeah.

Q. And it was a health-related issue that -- that somebody in the American market tried to take advantage of?

A. Well, there were two parts of it. One was -- well, here at the University of Wisconsin, found that phenol was a tumor promoter, phenol happened at reasonable levels at cigarette smoke.

Q. Uh-huh.

A. And that's what brought about concern about it. The business about somebody wanting to take advantage of it, I have no knowledge of the commercial -- whether somebody tried that for commercial gain or not.

Q. But -- but, in your opinion, is it an appropriate function of a research and development program to, in effect, try to pool information to avoid competition?

A. If you're saying that within a company, is it appropriate for BATCo to pool

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information to gain competitive advantage, I think that's entirely appropriate.

Q. And that's not the question I'm asking.

14:34 A. Okay.

Q. But what I'm asking is whether it is appropriate for BATCo and other market participants --

A. Oh, I see.

14:35 Q. -- to share information with the goal of preventing competition, in this case, on health issues.

A. I think that would be illegal in this country. I don't know whether it would be in the United Kingdom or not.

14:35 Q. But we talked earlier about your opinion that there -- you didn't find any information that BATCo or Brown & Williamson had that was not readily available in the open -- in the marketplace?

A. That's correct.

Q. Can you conceive of an arrangement whereby an agreement, either to share information or not develop information, could prevent competition that might otherwise occur

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on health issues, a safer cigarette?

A. That would be really stretching. You know, I -- trying to work through some scenario where that would -- would happen, and I -- I can't really come to grips with that.

Q. Okay. But you agree it would be inappropriate conduct?

A. Well, you know, like I said, in this country, it would be illegal.

Q. Let me show you what I'll mark as Exhibit 9, May 22nd, 1962 memorandum, and I tabbed on Page 2.

(Deposition Exhibit 9 was marked.)

Q. I'd like you to look at --

A. Memorandum from Green to Anderson. You want me to look at, what, Page 2?

Q. Yes, sir. And I bracketed, I think, a single sentence. If you would read that.

A. Where you have the policy?

Q. Yeah. As best I can.

MR. McGAAN: Was this among the documents? Do you know?

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14:37

MR. THOMPSON: Yeah.

MR. McGAAN: Supplied.

MR. THOMPSON: I think so. I think all these were.

14:37 A. I'm not sure about this one. I may have, you know, looked at a few thousand sheets of paper, but I --

MR. McGAAN: May I take a look at it before --

14:38 MR. THOMPSON: What's the Bates on it?

MR. McGAAN: 100159219.

MR. THOMPSON: What's the date, rather?

14:38 MR. McGAAN: May 22nd, 1962.

(Off-the-record discussion.)

THE VIDEOGRAPHER: We're off the record.

14:39 (A recess was taken.)

THE VIDEOGRAPHER: We're on the record.

Q. (By Mr. Thompson) Doctor, we're back to Exhibit 9, and if you would read the bracketed sentence for me that we tabbed.

14:46

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14:46 A. That sentence says, Apart from the last of these, which I understand the present policy is aimed to contribute along all these lines on an industry basis, and particularly, 14:47 for example, to eliminate exploitation of the situation by companies purporting short-term objectives with health claim.

Q. And would you agree with me that that is precisely the kind of arrangement that 14:47 you and I have been discussing about -- about pooling information to provide or to ensure against competitive advantage?

A. I guess I -- you know, I have a great deal of difficulty understanding how a 14:47 company is going to do this, get an advantage with health claims. You know, it's never been done by the tobacco industry, except back in the early days when doctors were smoking. But certainly from the middle '60s on, I can't 14:47 conceive -- I think it's a Don Quixote kind of thing. I think they're tilting a windmill that doesn't exist.

Q. Well, you've seen the new "No bull" ads for Winston, have you not?

14:48 A. Yeah.

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Q. What is your opinion about that? I mean, what -- is there an implied health claim there?

A. Absolutely not. I mean, no bull, no additives, pure tobacco. There's nothing about health in there at all.

Q. Okay.

A. It's the other way around as a matter of fact. I mean, you could read it -- you could read it as a downside ad.

Q. Saying I'll take it --

A. Stronger, more vigorous, tougher cigarettes. You think Marlboros are tough, wait till you smoke a Winston.

Q. I like that.

We've had a lot of discussion about reducing or attempting to reduce biologic activity.

A. Right.

Q. Are you familiar with the concept of smoker compensation?

A. Vaguely, yeah.

Q. Okay. And -- and the concept, I guess, stated in lay person's terms would be that -- that even a lower delivery cigarette

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14:49 that delivers a lower level of the incomplete products of combustion, the tar or the nicotine for that matter --

A. Right.

14:49 Q. -- will not really deliver a lower dose because the user will compensate by either smoking more cigarettes, smoking more quickly, sucking harder, holding it in longer, any number of factors.

14:49 Would you agree with me from a toxicological standpoint that that -- that compensation like that would certainly offset at least to some degree any advantage by lowered numbers in pure yield?

14:50 A. I think on a theoretical basis. Again, I -- I don't really have a good feel for the kind of data that are available on whether smokers actually do compensate and to what degree. I just don't know what that 14:50 information looks like, so that anything that I state is not based on -- on -- on -- that's the kind of information I would like, you know, I would like to know what fraction of smokers compensate, how much they compensate, 14:50 by what fraction. Then one could make some

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14:50 concrete scientific judgments about whether, in fact, they have reduced their exposure or not. But in the absence of that, it's very difficult.

14:50 Q. But certainly, it's a -- it's a concept, and an issue that the tobacco companies, including Brown & Williamson, BATCo, identified early on in this -- in this attempt to find a lower yield cigarette?

14:51 A. As did the surgeon general.

Q. You state -- or the summary of your opinion states that, in your opinion, the tobacco companies' position on causation, as you and I have discussed already today, has

14:51 had little or no impact on the assessments made or the judgments reached by the scientific, public health and medical communities with regard to smoking is dangerous. On what do you base that

14:51 conclusion?

A. Surgeon general's reports, articles in the -- articles in medical journals, you know, editorials I've seen in the -- you know, Journal of Public Health,

14:52 other journals, who have been, you know, some

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of them pretty bisferious in their condemnation of smoking.

Q. Uh-huh.

A. And I don't think that there has been any impact on those kinds of people by anything the tobacco industry has done.

Q. Okay. What about the tobacco industry's position on addiction as opposed to -- your opinion is limited. At least it's stated to causation --

A. Right.

Q. -- which I --

A. Which, in effect, cancer.

Q. Yes.

A. And some of the other things.

Q. What about addiction?

A. I don't understand.

Q. Is it also your opinion that -- that the tobacco companies' position, their -- their conduct with regard to the issue of addiction has had no impact upon the scientific, public health, medical communities?

A. Yeah. I mean, yeah. This -- especially with all the recent discussion out

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14:52 of FDA --

Q. Right.

A. -- and the surgeon general's reports. You know, they're very clear in what

14:53 they're stating.

Q. Sure. And I just -- you haven't -- other than just your kind of general feel for what you've read and working in the industry, you don't base that on any

14:53 specific information coming from the committee members of the surgeon's general -- the draft?

A. No. It's just a very -- it's just a general observation based on things that I have read.

14:53 Q. Uh-huh.

A. And the things that I have read certainly indicate to me that nothing the tobacco industry has said or done has either impacted -- impacted either the causation or

14:53 the addiction arguments that have been raised.

Q. And so if -- if somebody who was actually involved in decision-making process or the editing or the issuance of any of those reports testified to the contrary that, in

14:53 fact, it might have made a difference to me or

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to my committee, you wouldn't have any specific basis to disagree with that?

A. No, I wouldn't, but I'd be very surprised given the people I know who have served on the surgeon general's committee, that they would ever be swayed by that.

Q. Let me ask you -- we've kind of covered it in general, but what -- what did you do to prepare for your testimony in this trial, and specifically, for this deposition?

A. Just read boxes and boxes and boxes of material, and -- and talked briefly with Andy before -- before the deposition, telling me to listen closely to the questions, take a deep breath, answer only what you need to, and be factual and truthful.

Q. Those were good instructions, especially the first one since I asked such convoluted questions.

Did you meet with anybody else other than Andy?

A. No.

Q. Have you done any preparation in terms of practice testimony or videotaping your testimony in preparation for this?

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A. Nope.

Q. Have you prepared any -- other than the things that we've got floating around here, your -- the statement that I think Andy probably prepared for you --

A. We've --

Q. -- have you generated any --

A. We generated that together. We sort of sat down and -- sort of sat together and wrote it out, and then I -- I went back over it to make sure that I was very comfortable with it.

Q. Okay. Have you generated any other documents?

A. No. I have -- I have no documents other than covering letters for bills and invoices that I sent to Andy.

Q. Okay. Do you intend -- first of all, has Andy asked you to come to trial in September, Texarkana?

A. He has indicated that I might be called as a witness.

Q. Okay.

MR. McGAAN: But to be clear, trial is scheduled to start on the 29th, and

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you guys go first, so it may not be in September.

MR. THOMPSON: It may not. We'll be clear about that. It may be December.

Q. (By Mr. Thompson) Have you or do you intend to prepare any demonstratives to go with your general opinions and testimony?

A. We haven't really worked that out yet. I mean, we've talked about and thought about, you know, what are the kinds of things that would be useful to help me get my story across, but it's -- it's only been in, you know, sort of in the trial balloon stage, and we haven't put anything to paper or -- or anything yet.

Q. Okay. You are working as a consultant for -- for Brown & Williamson, correct?

A. That's correct.

Q. And you are charging them for your time?

A. That's correct.

Q. How much do you charge?

A. I charge 2,000 a day, 250 an hour,

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except for deposition or court appearance, when my rate doubles.

Q. Plus expenses?

A. Plus expenses at cost.

14:56 Q. And -- how do I decide between an hour and a day?

A. Well, if I work a whole day, it's a whole day.

Q. It's a discount?

14:57 A. If I -- well, it's not, you know. If -- if -- what, we spent five hours today, so it -- I'll charge him 10 hours for the deposition.

Q. Okay. The -- do you have any idea

14:57 how much you've billed to date on this case?

A. I have billed 13,250.

THE WITNESS: Is that right, Andy? We talked about that last night?

A. There are two invoices. I think one for 6,500.

MR. McGAAN: You're going to remember?

A. And 1,600 -- 1,600 -- 6,750. 13,250 is what I billed so far.

Q. (By Mr. Thompson) You testified

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previously that you're semi-retired. How much of your income do you derive from your consulting services that you do?

A. Oh, that depends how active it is, you know.

Q. On an average, take a couple years.

A. Oh, I would say on an average, probably around 60, 70 percent.

Q. And how much of your time have you spent consulting?

A. Ten to 20. That's a nice ratio, but I figured after 36 years, my time's worth a little bit.

MR. THOMPSON: Why don't we go off the record for a second.

THE VIDEOGRAPHER: We're off the record.

(A recess was taken.)

(Deposition Exhibit 10 was marked.)

THE VIDEOGRAPHER: We're on the record.

Q. (By Mr. Thompson) Doctor, I've got one thing I'd like to -- one document I'd

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like to show you in follow-up that's in my pile. I've marked it Exhibit 10. It's undated, and -- and take a look at it really quickly.

There are really two aspects that I'd like to look at. On the first page, it talks about objectives regarding products with lower biologic activity, and there's a subset that talks about a -- a low tar?

A. Medium delivery, low biological activity.

Q. Correct. And it talks about one of the advantages of why it might be an attractive product, and it lists one of the things that might do as to combat quitting.

How is it that something that in the -- in the race to try to create a lower biologic activity cigarette that by doing lower biologic activity with a moderate delivery that you're going to combat quitting?

A. You have to ask the author.

Q. Okay.

A. I don't have the foggiest idea. Quitting's not a biological decision.

Q. Okay.

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15:03 A. Quitting is a psychological decision, and delivery -- none of this has anything to did with quitting. I mean, quitting is something when someone makes up
15:04 their mind to do it. I don't see any connection, frankly, between biological activity and a decision to quit.

Q. Okay. Is -- in discussing delivery, what -- based on the context of that
15:04 statement, what is the delivery that they are discussing?

A. This is just a guess, but it's probably -- it's probably tar.

Q. So you've got a lower biologic
15:04 activity with moderate delivery, so you're talking about delivering tar in your opinion, as opposed to, for example, delivery of nicotine?

A. I -- you know, not having stated
15:04 it, I -- it's impossible to guess what it is, but delivery is -- is most often, I think, associated with -- with -- with tar and -- and, you know, how the mouth feels.

Q. Taste?

15:04 A. The taste, you know, how much --

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how much stuff are you getting in someone's mouth.

Q. So you wouldn't read that statement as -- as a statement setting an objective to try to lower biologic activity with -- with lowering the tar component of the yield, but keeping the delivery of -- of nicotine at a higher level to combat losing customer --

A. It's impossible. Without -- without specific words in here, you're -- you're just whistling Dixie trying to make that argument.

Q. Okay. On the last page, there's a discussion of effects on the foetus. Did you come across any documents discussing tests or studies or data relating to the effects of smoking on unborn babies or low birth weight babies?

A. The only place there was any discussion of that was in surgeon general's reports. I saw no, you know, research documents or -- or other pieces.

Q. Uh-huh.

A. And like we indicated earlier, I

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15:06 think the -- I think the epidemiological evidence as far as birth weight and smoking is pretty clear.

MR. THOMPSON: I will pass the witness.

15:06 MR. McGAAN: No questions at this time.

THE VIDEOGRAPHER: We're off the record.

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STATE OF TEXAS

COUNTY OF DALLAS

I, JAMIE K. ISRAELOW, a Certified Shorthand Reporter duly commissioned and qualified in and for the State of Texas, do hereby certify that there came before me on the 29th day of August, 1997 in the offices of Kirkland & Ellis, located at 200 East Randolph Drive, in the City of Chicago, State of Illinois, the following named person, to-wit: **ANDREW SIVAK, Ph.D.,** who was duly sworn to testify the truth, the whole truth, and nothing but the truth of knowledge touching and concerning the matters in controversy in this cause; and that he was thereupon examined upon his oath and his examination reduced to typewriting under my supervision; that the deposition is a true record of the testimony given by the witness, and signature of witness is to be before any notary public.

I further certify that I am neither attorney or counsel for, nor related to or employed by any of the parties to the action in which this deposition is taken, and further that I am not a relative or employee of any attorney or counsel employed by the parties hereto, or financially interested in the action.

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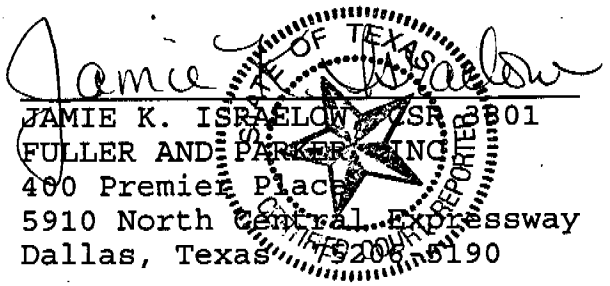

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